A COMPARATIVE STUDY OF HAEMODYNAMIC RESPONSE WITH LARYNGOSCOPIC ENDOTRACHEAL INTUBATION AND LARYNGEAL MASK AIRWAY INSERTION IN HYPERTENSIVE PATIENTS AT TERTIARY CARE HOSPITAL

DISSERTATION

SUBMITTED TO

THE TAMIL NADU Dr. M.G.R MEDICAL UNIVERSITY

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF

M. D. ANESTHESIOLOGY

BRANCH X

MAY 2019

DECLARATION

In the following pages is presented a consolidated report of "**A comparative study of haemodynamic response with laryngoscopic endotracheal intubation and laryngeal mask airway insertion in hypertensive patients at tertiary care hospital"**, on cases studied by me at Sree Mookambika Institute of Medical Sciences, Kulasekharam from 2016-2019. This thesis submitted to the Dr. M.G.R. Medical University, Chennai in partial fulfilment of the rules and regulations for the award of MD Degree examination in Anesthesiology.

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INTRODUCTION One of the most frequent and familiar methods of securing a definitive airway is laryngoscopy followed by endotracheal intubation during conduct of general anaesthesia.1

Direct laryngoscopy and intubation of the trachea inducing anesthesia are routinely associated with transient tachycardia, arrhythmias and hypertension.

The mechanisms underlying the hemodynamic responses are not completely understood, although they have been attributed to a reflex sympathetic discharge caused by stimulation of the upper respiratory tract. This speculation is supported by the previous observation that hemodynamic responses to direct laryngoscopy and tracheal intubation are associated with an increase in plasma catecholamine concentrations4,5 and are attenuated by β-adrenergic blockade.6

Brief tachycardia and hypertension are of limited consequences in healthy individuals, but both or either may be deleterious to the patients with hypertension, myocardial insufficiency or cerebrovascular disease.7 The choice of anesthesia becomes more of a concern in such patients because most of them are old, frail and with one or more associated systemic comorbidities.

The equivalent elevations in the heart rate and blood pressure are short lived and inconsistent, but these changes are more prominent and uncertain in hypertensive patients following laryngoscopy. As a consequence life-endangering complications such as pulmonary edema, cerebrovascular hemorrhage, and myocardial infarction, biventricular failure may ensue in susceptible patients.8

Patients with elevated blood pressure have high sympathetic nervous system activity. Hence, hypertensive

CERTIFICATE II

This is to certify that this dissertation work titled "**A comparative study of haemodynamic response with laryngoscopic endotracheal intubation and laryngeal mask airway insertion in hypertensive patients at tertiary care hospital**" of the candidate **Dr. Shrey Sharma** with registration Number 201620552 for the award of DOCTOR OF MEDICINE in the branch of Anesthesia. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows 1 percentage of plagiarism in the dissertation.

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Dr. Shrey Sharma

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LIST OF ABBREVIATIONS

ASA	:	American Society Of Anesthesiologist
BP	:	BLOOD PRESSURE
CVA	:	Cardio Vascular Accident
DAP	:	Diastolic Arterial Pressure
DBP	:	Diastolic Blood Pressure
DC	:	DIFFERENTIAL COUNT
DL/DLS	:	DIRECT LARYNGOSCOPY
ECG	:	ELECTROCARDIOGRAM
ESR	:	ERYTHROCYTIC SEDIMENTATION RATE
ETT / ET	:	ENDOTRACHEAL TUBE
G	:	GAUZE
HB	:	HEMOGLOBIN
HR	:	Heart Rate
ICU	:	INTENSIVE CARE UNIT
ID	:	INTERNAL DIAMETER
ILMA	:	Intubating Laryngeal Mask Airway
IOP	:	INTRA OCULAR PRESSURE
IV	:	INTRAVENOUS
KG	:	KILOGRAM
L/MIN	:	LITRES/ MIN
LMA	:	LARYNGEAL MASK AIRWAY

LMA-S	:	LARYNGEAL MASK AIRWAY – SUPREME
MAP	:	Mean Arterial Pressure
MCG	:	MICROGRAM
MCG/KG	:	MICROGRAM /KILOGRAM
MG / KG	:	MILLIGRAM / KILOGRAM
ML	:	MICRO LARYNGEAL TUBE
MM	:	MILLIMETER
OD	:	OUTER DIAMETER
PLMA	:	PROSEAL LARYNGEAL MASK AIRWAY
PONV	:	POST OPERATIVE NAUSEA AND VOMMITING
RPP	:	Rate Pressure Product
SAP	:	Systolic Arterial Pressure
SBP	:	Systolic Blood Pressure
TC	:	TOTAL COUNT

ABSTRACT

BACKGROUND

The hemodynamic response associated with laryngoscopy and tracheal intubation may be harmful to certain patients .The laryngeal mask airway avoids the need for laryngoscopy and provides positive pressure ventilation of the lungs in appropriate patients .

AIMS AND OBJECTIVES

This study compares the hemodynamic response of laryngoscopy and tracheal intubation to that of laryngeal mask airway insertion in hypertensive patients.

METHODS

60 Hypertensive patients between 40 to 60 years of either gender of ASA Grade II were randomly allotted to one of the groups of 30 each , group ET and group LMA .LMA insertion or tracheal intubation was performed after induction of anesthesia with Thiopentone and muscle relaxation with succinyl choline . Anesthesia was maintained with sevoflurane and nitrous oxide, oxygen the heart rate ,systolic BP, diastolic BP, mean arterial pressure and rate pressure product were measured after induction and immediately after insertion / intubation and then after 1 ,3,5 minutes .

RESULTS

There was very highly significant difference ($p < 0.000$) in mean increase in heart rate (38.23% in group ET versus 28.26% in group LMA). The increase in arterial pressure were also significant .The systolic BP increased 40.16% in group ET compared with 37.60% in group LMA ($p< 0.000$) . The diastolic BP was also seen increasing by 22.73% and 14.23% in group ET and group LMA respectively. The MAP and RPP values were maximum after airway instrumentation however we found that values after LMA insertion were significantly lower when compared to tracheal intubation for the first 3 minutes .

INTERPRETATION AND CONCLUSION

The data suggest a similar, but attenuated pattern of response associated with mask insertion in comparison to laryngoscopy and intubation .Hence use of LMA may therefore offer some advantages over tracheal intubation in anesthetic management of patients where avoidance of pressure response is of particular concern.

INTRODUCTION

One of the most frequent and familiar methods of securing a definitive airway is laryngoscopy followed by endotracheal intubation during conduct of general anaesthesia.[1]

Direct laryngoscopy and intubation of the trachea inducing anesthesia are routinely associated with transient tachycardia, arrhythmias and hypertension.[2,3]

The mechanisms underlying the hemodynamic responses are not completely understood, although they have been attributed to a reflex sympathetic discharge caused by stimulation of the upper respiratory tract. This speculation is supported by the previous observations that hemodynamic responses to direct laryngoscopy and tracheal intubation are associated with an increase in plasma catecholamine concentrations[4,5] and are attenuated by β-adrenergic blockade.[6]

Brief tachycardia and hypertension are of limited consequences in healthy individuals, but both or either may be deleterious to the patients with hypertension, myocardial insufficiency or cerebrovascular disease.[7] The choice of anesthesia becomes more of a concern in such patients because most of them are old, frail and with one or more associated systemic comorbidities.

The equivalent elevations in the heart rate and blood pressure are short lived and inconsistent, but these changes are more prominent and uncertain in hypertensive patients following laryngoscopy. As a consequence life-endangering complications such as pulmonary edema, cerebrovascular hemorrhage, and myocardial infarction, biventricular failure may ensue in susceptible patients.[8]

Patients with elevated blood pressure have high sympathetic nervous system activity. Hence, hypertensive patients may show a magnified blood pressure and heart rate response to both laryngoscopy and intubation, which is not the case in normotensive patients.[9,10]

Laryngoscopy and endotracheal intubation are noxious stimuli capable of producing a huge spectrum of stress responses such as tachycardia, hypertension, laryngospasm, bronchospasm, raised intracranial pressure and intraocular pressure.[11]

Reflex changes in the cardiovascular system are most marked after laryngoscopy and intubation and lead to an average increase in blood pressure by 40-50% and 20% increase in heart rate.[12]

The effects of anesthesia on the circulatory system in both patients who are on treatment and without treatment for hypertension, there are 3 stages of haemodynamic instability [13], as according to previous studies,

- Direct laryngoscopy and tracheal intubation
- After removal of laryngoscope
- Immediately during incision

This happens due to release of catecholamines in the circulation causing increased oxygen demand[14].

Insertion of laryngeal mask airway (LMA) designed and advocated by Brain, has been broadly used in airway management for superficial and limb surgeries in selected populations.

LMA placement, post anesthesia induction causes reduced haemodynamic changes than tracheal intubation.

The laryngeal mask airway has proved to be a well-known addition to the range of equipments available for managing the airway. The transitional design of the LMA has shown to fill a hallow between ET and oropharyngeal airway. The intermediate design of LMA while ruling out the drawbacks of ETT was introduced to provide some of the advantages over ETT. This is because the glottis is not visualised and not opened. In this comparative study, the hemodynamic stress response to insertion of laryngeal mask airway and laryngoscopic tracheal intubation in hypertensive patients were assessed.

AIMS AND OBJECTIVES

- To study the hemodynamic response in hypertensive patient after direct laryngoscopy and endotracheal intubation.
- To study the hemodynamic response to laryngeal mask airway insertion in hypertensive patients.
- To compare the hemodynamic response in hypertensive patients to laryngoscopic endotracheal intubation with laryngeal mask airway insertion.

HYPOTHESIS:

LMA insertion is safer in hypertensive patients because it produces less stress response and therefore better hemodynamic stability and less end organ damage.

SCIENTIFIC JUSTIFICATION:

The widely used method to stabilize the airway for administering anaesthesia is via laryngoscopy and ETT. Although tachycardia and hypertension are most common complications which accompanies along.[19]

The reaction to laryngeal and tracheal stimulation is a reflex discharge of catecholamines from sympathetic nervous system in turn causing elevations in BP and heart rate. This process is called hemodynamic stress response.[20]

Measures for controlling the hypertensive responses to laryngoscopy and intubation aim to stabilise the blood pressure during induction of anesthesia in order to preserve perfusion of vital organs.[21]

Measures for controlling the blood pressure response to laryngoscopy and intubation aim to stabilise blood pressure during induction of anesthesia in order to preserve perfusion of vital organs.

Pharmacological methods to reduce, the stress response to laryngoscopy and endotracheal tube insertion includes the use.[22]

- Esmolol
- Lidocaine
- Nitroglycerine
- Magnesium Sulphate

- Verapamil
- Nicardipine
- Diltiazem

The hypertensive response to laryngoscopy with endotracheal intubation may be harmful in patients with high intra cranial pressure, cardiovascular disease, or central vessel anomalies.

REVIEW OF LITERATURE

The history of endotracheal intubation

Dating back to 3600 BC, the depiction of tracheotomy was first seen on two Egyptian tablets..[24]

Tracheotomy was described in an ancient Indian scripture, the Rigveda: the text mentions "the bountiful one who, without a ligature, can cause the windpipe to re-unite when the cervical cartilages are cut across, provided they are not entirely severed.[25,26,27]

Homerus of Byzantium is said to have written about Alexander the Great (356–323 BC) saving a soldier from asphyxiation by making an incision with the tip of his sword in the man's trachea.[28]

Asclepiades of Bithynia (ca. 124–40 BC) was the first physician to be credited of performing a non-emergency tracheotomy, despite the contribution of Hippocrates, Galen of Pergamon (129–199) and Aretaeus of Cappadocia(both of whom lived in Rome in the 2nd century AD).[29]

A Spanish vocal pedagogist named Manuel García(1805–1906), in 1854 was became the first man who viewed the functioning glottis in a living human being. García developed a tool that used two mirrors for which the Sun served as an external light source.[30]

The first person to report the profound rate of success of direct laryngoscopy : a way to tracheal intubation, was Chevalier Jackson .[31]

Sir Robert Reynolds Macintosh (1897–1989) also achieved significant advances in techniques for tracheal intubation when he introduced his new curved laryngoscope blade in 1943.[32]

The pioneers of modern anesthesia and technology[33]

The Macintosh curved laryngoscopic blade was invented by Sir Robert Reynolds Macintosh. The blade is most frequently used laryngoscopic blade for orotracheal/ nasotracheal intubation till today.

P. Hex Venn developed an endotracheal tube introducer

Robert Miller described the straight laryngoscope blade

Dr. Archie Brain invented the LMA

ANATOMY OF THE UPPER AIRWAY[33,34]

The nose and mouth to the glottis forms the upper airway. The upper airway consists of the pharynx and the nasal cavities.

The pharynx is can be divided into the

- Nasopharynx,
- Oropharynx
- Laryngopharynx.

The upper and the lower respiratory tract is divided into two parts by cricoid cartilage.

Nasal cavity and Nasopharynx

Formed by union of facial bones. Nasal floor towards ear and not eye is lined with mucous membranes. Cilia tissues are delicate and vascular, the lymphoid tissue filters bacteria

Nasopharynx or the Postnasal space

- ✓ The roof of the nasopharynx is formed by the body of sphenoid and basi-occiput.
- ✓ The floor by the soft palate
- ✓ Posteriorly it is related to the upper cervical vertebrae
- ✓ Anterior relation is the nasal cavity
- ✓ Laterally it is related to the eustachian tube and pharyngeal recess.

Oral cavity and Oropharynx

The palate is the boundary which separates oropharynx and nasopharynx. The area of the oropharynx is of prime importance to the anaesthetist in his daily life.

The Anterior relations of the oropharynx are formed by the palatoglossal and palatopharyngeal arches

Superior relations are the soft palate.

Inferior relation is Epiglottis.

Posterior relations are second and third cervical vertebrae

Parts of the Oropharynx

- Epiglottis a leaf-like structure which closes during swallowing and prevents aspiration of food and saliva into the respiratory tract.
- Vallecula formed by base of tongue.
- Larynx attached to hyoid bone is horseshoe shaped bone and supports trachea

Laryngopharynx

Anterior relations of the laryngopharynx is the larynx, the posterior relations of the laryngopharynx is formed by fourth, fifth, sixth cervical vertebrae .Relations of the laryngopharynx superiorly is the oropharynx and inferiorly the esophagus..

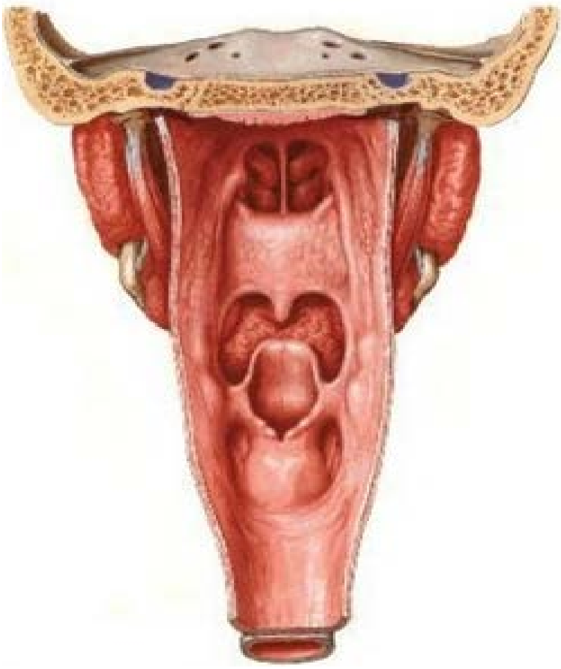


Fig. 1: The Pharynx

The Blood supply of the pharynx[34]

Blood supply of the pharynx is by both internal and external carotid arteries. The pharynx is supplied by pharyngeal branch of maxillary artery and lingual artery ascending pharyngeal, superior thyroid arteries

Venous drainage

Venous drainage is to the ophthalmic and facial veins and the pterygoid and pharyngeal plexuses. Venous drainage is, therefore, both intracranial and extra cranial.

Nervous innervation

Nervous supply of oral cavity:

- Facial nerve
- Glossopharyngeal nerve
- Trigeminal nerve
- Hypoglossal nerve

Nervous supply of nasal cavity:

- Infra Orbital Branch Of Maxillary Nerve
- Anterior Ethmoidal Nerves
- Posterior Ethmoidal Nerves
- Anterior-Superior Alveolar Branch of Maxillary Nerve

Glossopharyngeal nerve supplies:

- Upper epiglottis
- Base of the tongue
- Wall of pharynx

Structures supplied by Superior laryngeal nerve:

Supraglottic parts of the pharynx

Lower epiglottis

- Both the superior and recurrent laryngeal nerves supplies the mucous membrane of larynx.
- Inferior ganglion of Vagus along with small branch from superior sympathetic ganglion forms the Superior laryngeal nerve.

Superior laryngeal nerve divides into two branches:

Internal branch

External branch

The division takes place at the level of greater horn of hyoid.

The sensory supply to structures is via internal branch

The structures supplied by upper branch of superior laryngeal nerve:

Vestibule of the larynx

Epiglottis

Vallecula

The mucous membrane of the lower pharynx.

Cricothyroid muscle is supplied by superior laryngeal nerve but the remaining muscles of the larynx are supplied by recurrent laryngeal nerve.

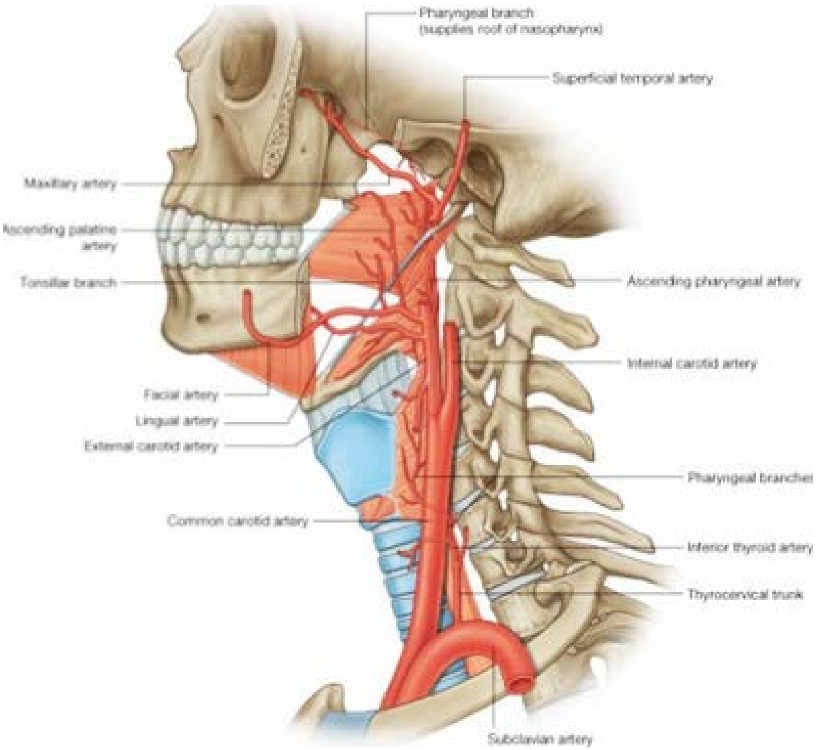


Fig. 2: The Blood supply of the pharynx

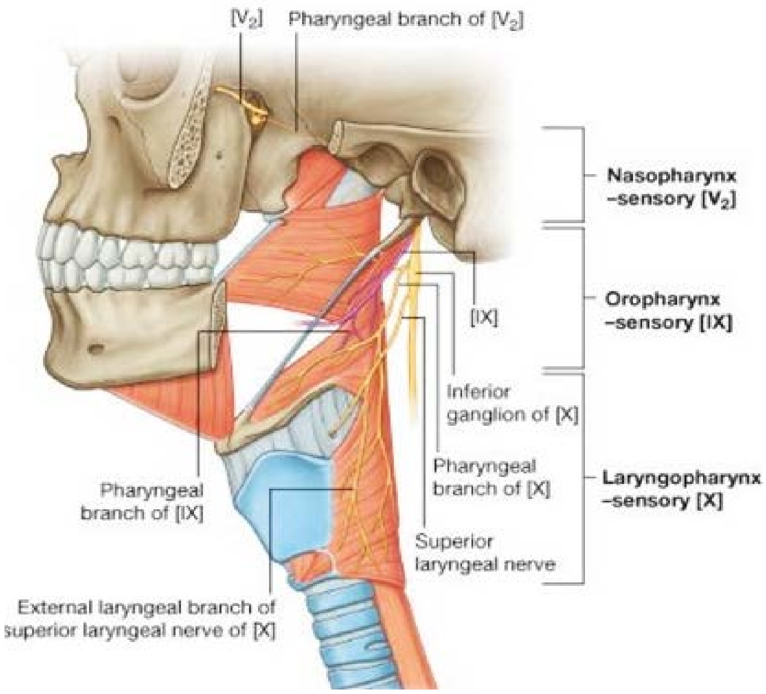


Fig. 3: Nervous innervation of the Pharynx

Tracheal intubation[33]

Endotracheal intubation is routiney performed with the help of a tube made up of polyvinyl chloride commonly known as tracheal tube.

It is available in various sizes according to the age, gender and weight

Functions of the endotracheal tube includes following:

- Maintains patency of the airway.
- Used in operation theatres for surgeries elective and emergencies
- Used in ICUs, emergency departmnts as a life saving device during cardio pulmonary resuscitation to ventilate lungs.
- In emergencies of asphyxiation and airway obstruction ventilation.
- Used as a conduit to administer drugs like salbutamol and ipratropium bromide.
- Avoids aspiration of gastric contents.

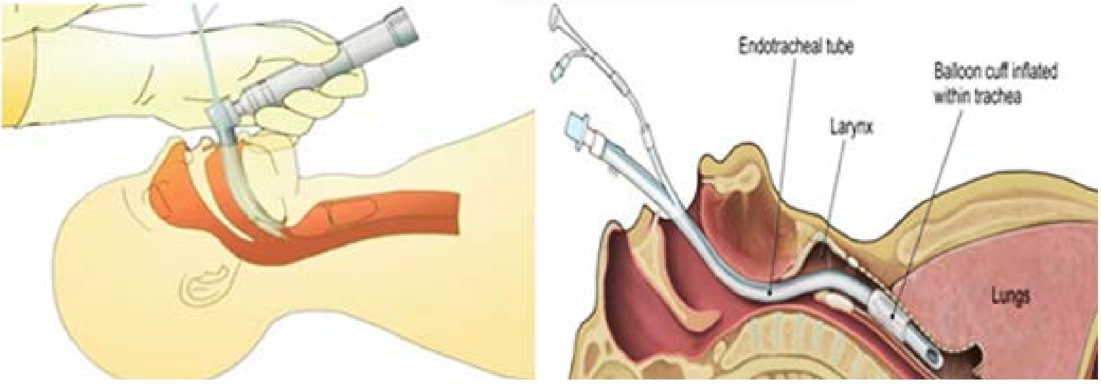


Fig. 4: Tracheal intubation

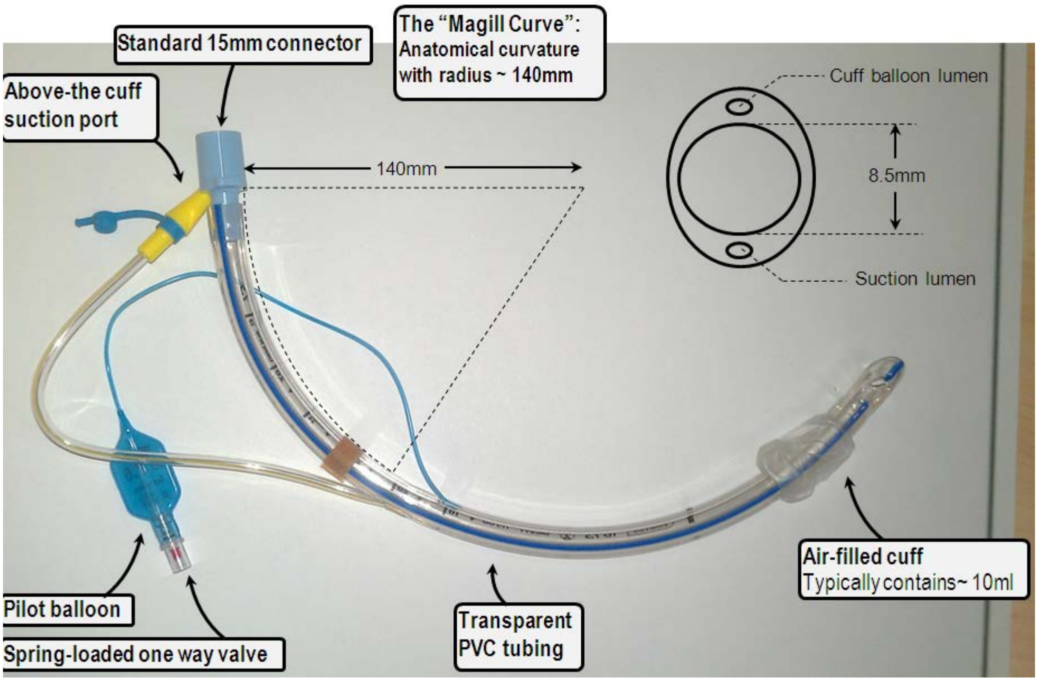


Fig. 5: Parts of endotracheal tube

Technique

- Before attempting the insertion of an ETT and as indicated by clinical condition, one should ventilate with bag and mask using 80-100% oxygen. If unable to insert the ETT under 30 seconds, one should ventilate again for 3 minute before reattempting intubation.

- Head should be slightly extended (in the sniffing position) with the body aligned straight.

- The laryngoscope is held with the left hand. Pushing down gently on the larynx with the fifth finger of the left hand (or having an assistant do it) to provide slight cricoid pressure to easily visualize the vocal cords. Avoid extreme tension or tilt of the laryngoscope to introduce the tube.

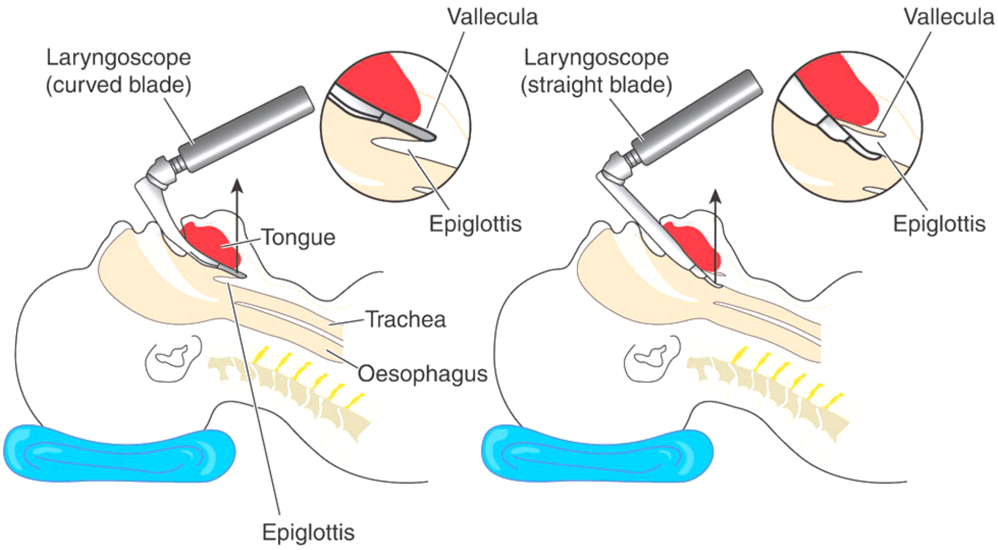


Fig. 6: Insertion technique

Indications for intubation

- Administration of surfactants or other medications directly into the lungs.
- To relieve critical upper airway obstruction.
- For mechanical ventilatory support in ICU's treatment.
- For selective bronchial ventilation- one lung ventilation
- For assisting in pulmonary hygiene when secretions cannot be otherwise cleared.
- For obtaining direct tracheal cultures.

- To protect the airway in case of

  Obstruction

  Facial trauma

  If patient is unconscious

- For treatment of profound hypoxaemia and respiratory failure
- To initiate positive pressure ventilation, in elective/emergency, for patients with pneumonia or cardiogenic shock
- To facilitate tracheal suction and the removal of secretions
- To maintain respiratory function during surgery/anesthesia

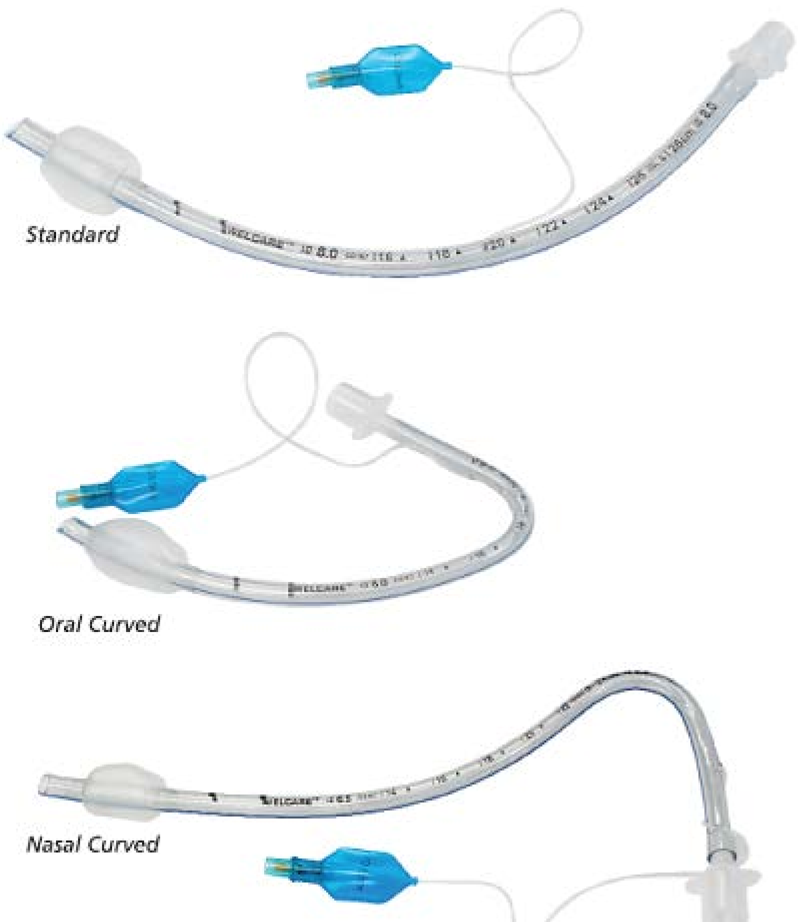


Fig.7: Types of tracheal tube

TYPES OF ENDOTRACHEAL TUBE

1. Cuffed Murphy endotracheal tube
2. Magell type tube
3. Cole Tube
4. Armoured endotracheal
5. Laser resistant endotracheal tubes
6. Double lumen tubes
7. Hunsaker Mon-Jet Ventilation Tube
8. Laryngectomy Tube
9. Microlaryngeal Tracheal Surgery Tube
10. RAE- Ring Adair Elwin

Post-Intubation Complications

The complication of intubation can be classified under

1. Complications seen during the act of intubation

- Failed intubation
- Spinal cord and vertebral column injury
- Occlusion of central artery of the retina and blindness
- Corneal abrasion
- Disconnection and dislodgement
- Acute traumatic complications :-
    - ✓ Trauma to lips
    - ✓ Teeth
    - ✓ Tongue
    - ✓ Nose

- Noxious autonomic reflexes
- Hypertension, tachycardia,
- Bradycardia and arrhythmia
- Raised intracranial and intraocular tension
- Laryngospasm
- Bronchospasm
- Laryngeal trauma
- Cord avulsions,
- Fractures and dislocation of arytenoids
- Airway perforation
- Trauma of

    Nasal

    Retropharyngeal,

    Pharyngeal,

    Uvular,

    Laryngeal,

    Tracheal,

    Oesophageal

    Bronchial Trauma

- Oesophageal intubation

2. Complications while the endotracheal tube is in situ

- Tension pneumothorax
- Pulmonary aspiration

- Disconnection and dislodgement
- Tracheal tube fire
- Unsatisfactory seal
- Leaky circuits
- Swallowed ETT

3. Complications during Extubation

- Difficult extubation
- Cuff related problems
- ETT sutured to trachea or bronchus
- Laryngeal oedema
- Aspiration of oral or gastric contents

4. Complications post-extubation

- Sore throat
- Laryngeal oedema
- Nerve injury
- Hoarseness
- Laryngeal granuloma
- Glottic and subglottic oedema
- Granulation tissue
- Laryngeal synechiae
- Vocal cord paralysis
- Aspiration
- Tracheal stenosis

- Tracheomalacia
- Tracheo-oesophageal fistula
- Tracheo-innominate fistula

Factors contributing to complication of intubation

1. Improper intubation technique
2. Improper tube size
3. Improper inflation of the tube cuff

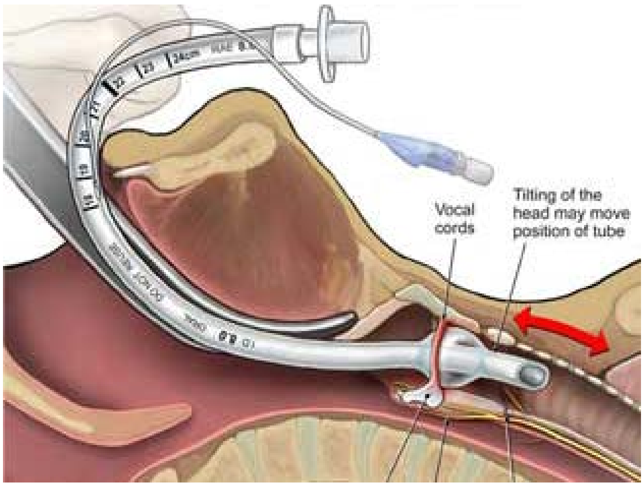


Fig. 8: Factors contributing to complication of intubation: Improper intubation technique

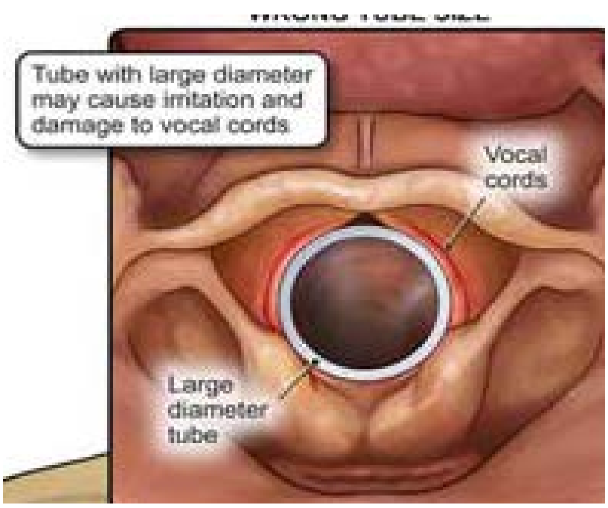


Fig. 9: Factors contributing to complication of intubation: Improper tube size

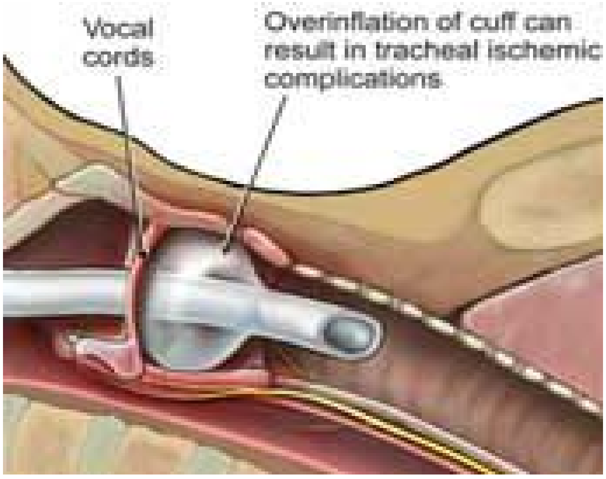


Fig. 10: Factors contributing to complication of intubation: Improper inflation of the tube cuff

The laryngeal mask airway[38]

Dr. Archie I.J Brain designed laryngeal mask airway in 1981.

He designed LMA, as a segment of a specific search for the airway.

The purpose was to make it less intrusive than the endotracheal tube but more in empirical than the face mask.

The LMA encloses the larynx by forming a seal without leak, hence avoiding its plugging to pharynx and in turn obstruction of the airway in the oropharynx**.**

Fig. 11: Dr. Archie Brain

Description of a Standard LMA

LMA is made up of silicone. The standard LMA has a shaft curved at an angle joined to a wide mouthed spoon shaped cup at an angle of 30°.There are two malleable straight bars where the tube attaches to the mask in order to prevent any obstruction to the lumen by the epiglottis. Presence of a self sealing pilot ballon at the proximal part of the mouth of the LMA makes it easy to fix during surgeries after inflation. A straight black line runs along the lateral aspect of the shaft. At the end of the shaft distally there is a 15 mm universal connector.

Physiological effects

When the pilot balloon is inflated with air, the elliptical bars increases in size and snuggly fits around the pharynx. This creates a pressure in the capillaries of the pharyngeal mucosa, causing decrease in the capillary perfusion pressure.

However because of the relaxation caused by muscle relaxants during general anaesthesia, there is not much decrease in capillary perfusion pressure of the pharyngeal wall.[36]

Since the diameter of the lumen of LMA is larger than that of ETT, the resistance imposed to flow is comparatively less.[37]

There is a change in the blood pressure and heart rate which are transiently elevated after securing airway with LMA. Although the increase is not as high as tracheal tube but it is more or infact similar to insertion of Guedel's oropharyngeal airway. The heart rate returns to baseline values in shorter span of time than it returns after tracheal intubation.[17]

Studies also suggest that increase in IOP is higher when general anaesthesia is conducted with the help of LMA than when it is conducted with ETT.[38]

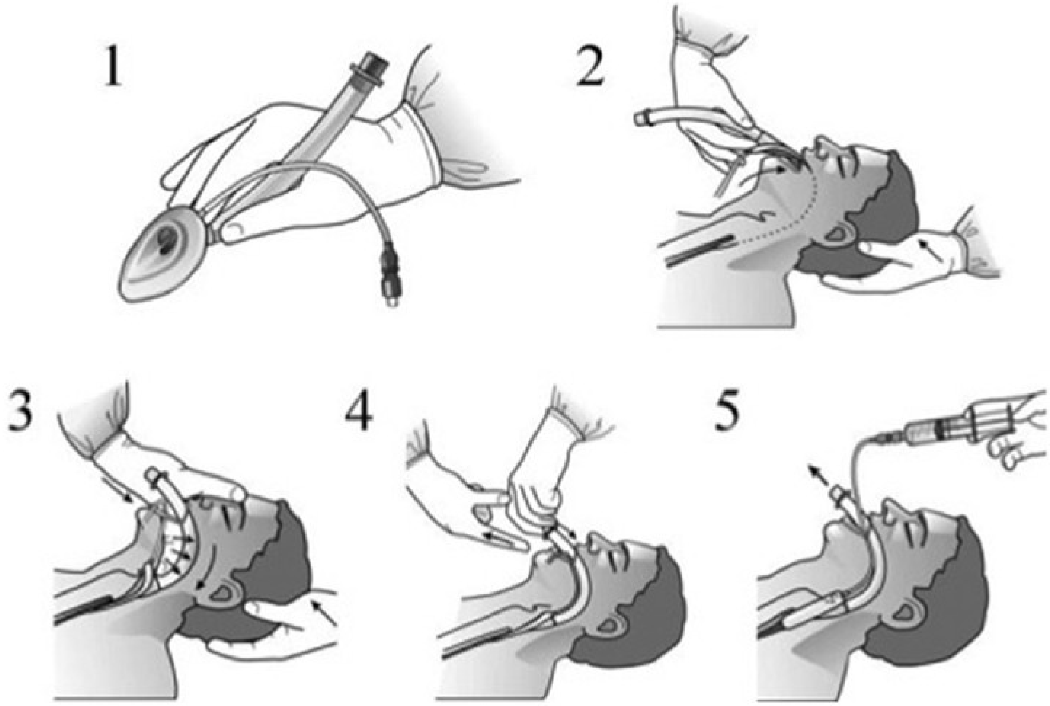


Figure 12: Technique of Inserting LMA

Available Laryngeal mask airways[33]

Size	ID in mm	OD in mm	Patient size
1	5.25/8.2	8	Neonates/infants upto 5 kg.
1.5	6.1/9.6	10	Infants between 5-10 kg.
2	7.0/11.0	11.0	Infants /children between 10-20kg
2.5	8.4/13.0	12.5	Children between 20-30kg
3	10/15	16	Children and small adults over 30-50 kg.
4	10/15	16	Normal adults (50-70 kg)
5	11.5/16.5	18	Large adults >70kg

The laryngeal mask airway has been designed to form a seal around the larynx with the distal part of the mask conforming to the hypopharynx and the wall of the long axis of the mask facing towards the pyriform fossae. The seal is usually so effective that controlled ventilation may well be possible without an obvious peri laryngeal leak.

It is extremely useful in securing airway in patient who are difficult to intubate, but who have adequate mouth opening. The vocal cords are not normally encroached which avoids the problems of laryngeal spasm associated with insertion or removal of endotracheal tube.

The appropriate anatomic position occupied by the Classic LMA is as follows:

The mouth of the LMA snuggly rest on the hypopharynx where oesophagus and respiratory tract divides. It seals the glottis with comparatively lower pressure. Hence the epiglottis press at the tip of the mask. Above, proximal part of LMA lies at the base of the tongue.

When the cuff of the LMA is inflated the proximal part covers the base of the tongue. The lateral part covers the pyriform fossa. And the tip lies just above the vocal cords making the epiglottis rest at it.

If properly placed the aperture of LMA has to be in proper alignment with the laryngeal inlet.

When appropriately placed, tip approximately lies posterior to cricoid cartilage. Anterior to C2-C7 cervical vertebra is posterior surface of the LMA.

Indications[39,40,41]

- Elective/emergency below head and neck short surgical procedures under general anaesthesia.
- It can be used as a rescue instrument "in cannot intubate – cannot ventilate" situations. The reason behind it being the ease and successful placement of LMA without much technical difficulties. Whereas on the other hand ETT requires difficult instrumentation and airway handling.
- Cardiopulmonary resuscitation

Contraindications[42,43]

- Oropharyngeal injuries
- Poor lung compliance
- Airway pressure more than 20 cm of H2O
- Non fasting patients
- Surgeries where bowel distension is to be avoided.

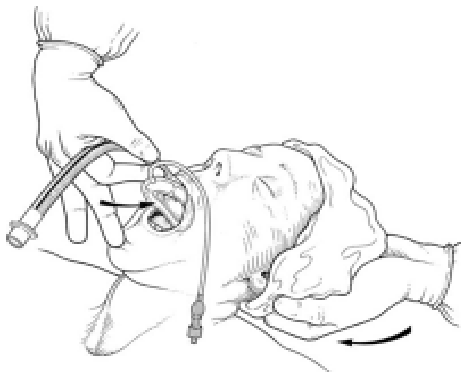
Insertion technique[33]

LMA insertion can be contemplated in the situation of swallowing both in terms of space occupied and the types of reflex response caused by it. No laryngoscope / muscle relaxant is required for insertion technique.

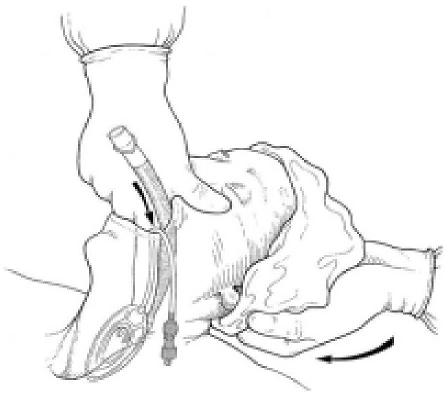
Standard Technique[33]

- The cuff should be partially/ fully deflated while choosing either a midline or diagonal approach to enter the mouth according to individual variability.
- Routinely the non dominant hand plays a major role in placing the LMA.

- Unlike tracheal intubation, no position of the head or axis alignment is needed to introduce LMA. Sometimes the jaw has to be kept open by the assistant to help introducing the device.
- The LMA is held as a pen, the mouth kept opened with the help of assistant, index finger of the same hand on the portion joining bowl with shaft, LMA is introduced.



Initial insertion of the laryngeal mask. Under direct vision, the mask tip is pressed upward against the hard palate. The middle finger may be used to push the lower jaw downward. The mask is pressed upward as it is advanced into the pharynx to ensure that the tip remains flattened and avoids the tongue. The jaw should not be held open once the mask is inside the mouth. The nonintubating hand can be used to stabilize the occiput. (Courtesy of Gensia Pharmaceuticals, Inc



By withdrawing the other fingers and with a slight pronation of the forearm, it is usually possible to push the mask fully into position in one fluid movement. Note that the neck is kept flexed and the head extended. (Courtesy of Gensia Pharmaceuticals, Inc

Fig. 13: Insertion of LMA

Pathophysiology[43,44]

At low to average cuff pressures, the capillary perfusion pressure in the pharyngeal mucosa, is not as much altered, except for ILMA. The reason being, its non-invasive nature, as it does not pierces the cord and hence no alterations in cardiovascular and respiratory functions.

Further do to non-penetration of the cords sore throat is seen less as a complication. Although during insertion of LMA greater depths of anaesthesia are required, once the LMA is in situ the depths of anaesthesia becomes drastically less when compared to ETT.

Also the pressure response to LMA are less during all phases of anaesthesia like:

- Intubation
- Maintenance
- Extubation

LMA variants[33]

1. LMA- classic
2. Reinforced / Flexible LMA (LMA-Flexible),
3. LMA specifically designed for tracheal intubation (LMA-Fastrach),
4. Single-use LMA (LMA-Unique)
5. LMA with an integral gastric access/ venting port (LMA-ProSeal).
6. LMA C Trach

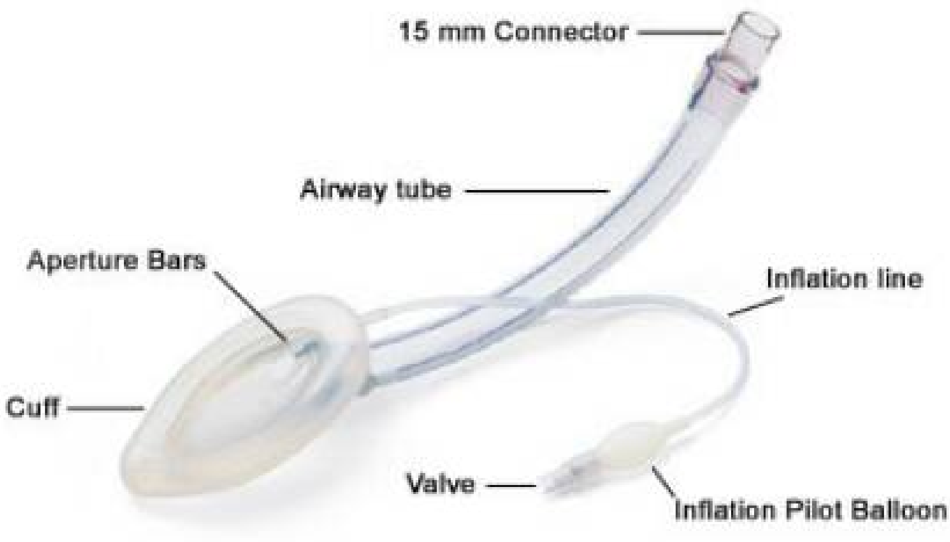


Fig. 14. The Classic LMA

Fig. 15: THE LMA RE - INFORCED

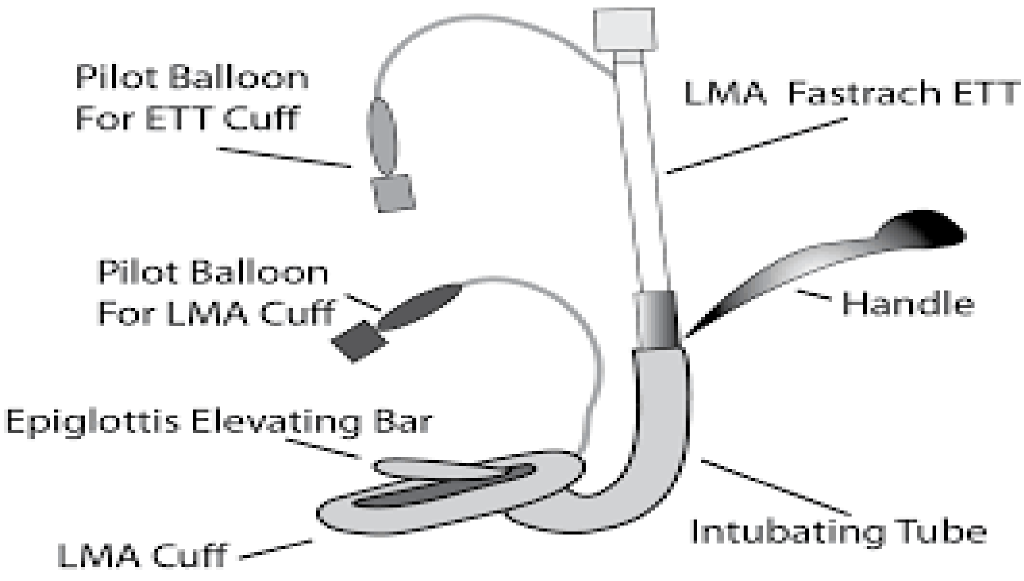


Fig. 16 LMA FASTRACH

Fig. 17 LMA UNIQUE

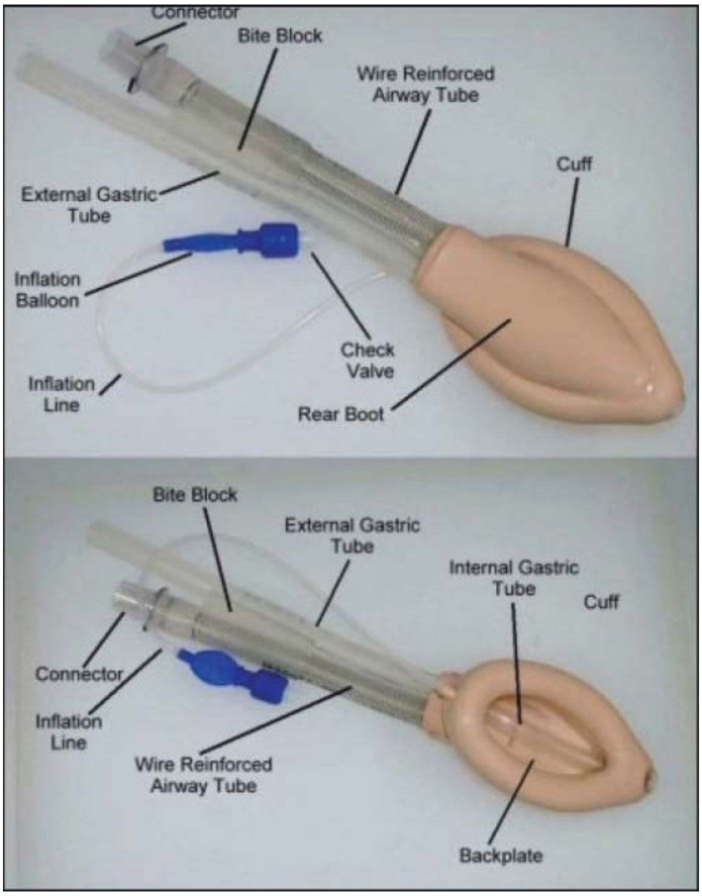


Fig. 18: LMA PROSEAL

Fig. 19: LMA C-TRACH

Advantages and disadvantages of LMA compared to ETT Advantages[33]

Advantages

- Easier placement
- Less cardiovascular response
- No laryngoscopy needed
- Minimal intraocular pressure rise
- Non invasive airway device
- Avoids oesophageal and endobronchial intubation
- Smooth emergence
- Better tolerated

Disadvantages

- Airway not as secure as ETT
- Risk of aspiration
- Gastric insufflation more likely.
- Unsuitable for collapsible airway

Modifications to the standard LMA-Classic involving slight changes retaining the same overall structure and shape of the standard LMA include the

- LMA Supreme has a built-in bite block.
- LMA-ProSeal, has an accessory port just parallel to ventilation port to support removal of secretions during and after the surgeries in order to avoid pulmonary aspiration of gastric contents.
- LMA-Unique and
- LMA-Flexible has softer tubing.

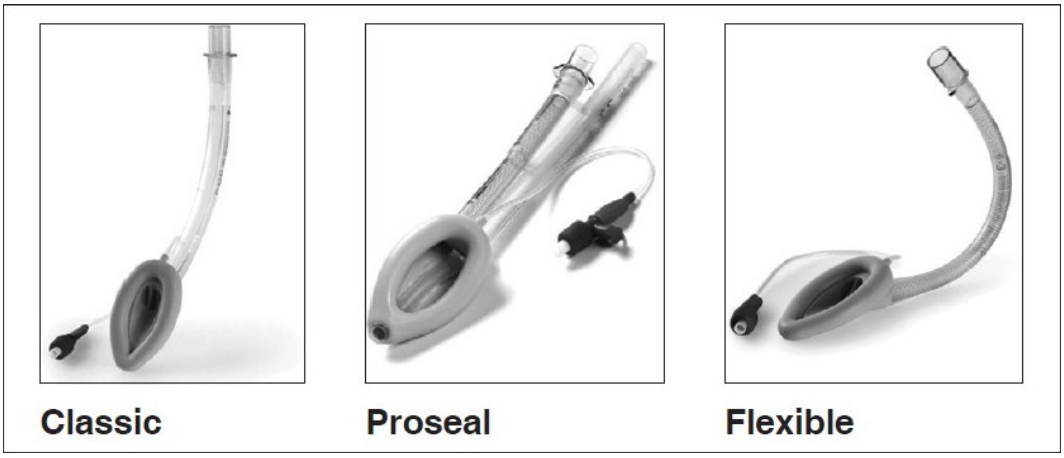


Figure 20: Types of LMA

Physiology of the airway reflexes:

There are abundant sensory receptors in epiglottis, lower part of pharynx and larynx.

These receptors are sensitive to various stimulations including:

- Chemical stimuli
- Thermal stimuli
- Mechanical stimuli

Although out of three, receptors are not sensitive to mechanical stimulation.

Any stimulus applied and sensed by tube receptors causes following response:

- Tachycardia
- Hypertension
- Cough
- Hiccup
- Release of endogenous catecholamines
- Increased intra cranial pressure
- Increased intra ocular pressure
- Reflex sympathetic stimulation

Sensory supply to mucosal epithelium of airway has free nerve endings mostly seen on the arytenoid cartilage and epiglottis.

The nerve fibres of afferent impulses of superior laryngeal nerve to CNS are small in diameter myelinated in nature:

- Group III fibres
- A-delta fibres
- B sensory fibres

They all carry afferent impulses.

Inferior surface of vocal cord as supplied by Recurrent laryngeal nerve is sensory in touch. The above mentioned afferent fibres of the recurrent laryngeal nerve and superior laryngeal nerve goes and relays information to nucleus tractus sollitarius. This in turn is transmitted to medulla and vasomotor centre.

Vasomotor centre together known as

- Lower pons
- Upper part of medulla

Give rise to sympathetic activity as received by afferent impulse. As observed earlier afferent impulses receive stimulus from mechanoreceptors.

They are located in the

- Heart
- Arteries
- Lungs

Efferent sympathetic route is divided into pre ganglionic and post ganglionic impulse.

The pre-ganglionic neurons of cell bodies lies within:

- Thoracic
- Upper lumbar spinal cord

The pre-ganglionic impulse via anterior part of spinal neurons. Through white ramus passes the spinal cord.

Post ganglion has cell bodies in the sympathetic chains. They synapse at the ramus and supply the effector organ. Stimulation of receptor causes the entry pathway activation. This further causes release of catecholamines from medulla of adrenal gland which is perceived as pressor response.

Response to laryngoscopy and intubation:

In adults where we see a potent sympathetic stimulus after direct laryngoscope and intubation, in pediatric this stimulus causes bradycardia and laryngospasm.

This can be attributed to predominant vagal tone in this age group.

There is cerebral vasoconstriction and hence increase in response to direct laryngoscopy and intubation.

All the above can be contributed to involvement of sympathetic ganglia and cardiac sympathetic fibres.

Mediators of cardiovascular response:

- Release of adrenaline from adrenal medulla and it acts on blood vessels, heart and thus increases BP and heart rate.

- Activation of renin-angiotensin system. It leads to aldosterone formation which causes water retention, increased blood volume, increased heart load and increased cardiac output.
- Secretion of epinephrine from adrenal medulla
- Secretion of norepinephrine from synapses

Braude N et al (1989) studied the Hemodynamic responses of that of laryngeal mask insertion to tracheal intubation. It was shown that a similar, but obtunded pattern of response was seen in laryngeal mask insertion in comparison to laryngoscopy and intubation, evident changes between the two were seen in arterial diastolic blood pressure soon after and again 120 seconds after insertion. In the anesthetic management of patients where hemodynamic responses cannot be avoided and is of utmost concern, use of laryngeal mask airway edges over tracheal intubation by far.[16]

In 1992; Wilson et al compared hemodynamic responses to Laryngeal Mask airway insertion to that of Tracheal tube and inferred that there is a minimal yet not marked rise in arterial pressure in both diastole and systole. These values was considerably less, and significantly so, when compared to that associated with laryngoscopy and tracheal intubation. Hence, they found that there was an reduced cardiovascular response to insertion of the LMA when compared with tracheal intubation. The use of the LMA can be useful therefore in situations where the hemodynamic response to intubation has to be avoided, e.g. during induction of anesthesia and controlled situation of an unexpected difficult airway in the hypertensive patient.[17]

N.M. Denny et al 1993, conducted a study to compare complications during general anesthesia in a cataract surgery while putting Laryngeal mask airway and tracheal tube and concluded that there is a significantly lower incidence of coughing in patients whose airway was controlled using a laryngeal mask airway than in those whose airway was secured with a tracheal tube. They also said that there was higher incidence of coughing before extubation ($P< 0.001$), where extubation ($P< 0.001$) and after extubation ($P< 0.001$) in the tracheal group than in the laryngeal mask airway group. No other complications were seen in either of the group.[45]

In 1995, Fujii et al studied the effects of insertion of LMA and tracheal intubation in hypertensive and normotensive patients . They concluded that after tracheal intubation or LMA insertion at baseline ($P <0.05$), there was an elevation in the heart rate and MAP, in both patients having high blood pressure and those who were normal. Post LMA insertion ($P <0.05$) changes in hemodynamics were less compared to intubation. Hence LMA is safer in hypertensive patients due to less haemodynamic changes.[9]

Joshi et al in Sep 1997 suggested that the LMA is a useful alternative to the TT for airway management during ambulatory anesthesia as they did a prospective, randomized, multicenter study to compare anesthetic requirements, recovery times, and postoperative side effects when a laryngeal mask airway (LMA) was used as an alternative to the tracheal tube (TT) during ambulatory anesthesia. Hence they inferred that the use of the Laryngeal mask airway can obviate the need for insertion of a Tracheal tube for many ambulatory surgery procedures, and thereby decrease the incidence of postoperative sore throats.[46]

In1999, Oczenski et al concluded that the insertion of a LMA would elicit a much smaller hemodynamic and catecholamine response than tracheal intubation and significantly lower than combitube. They further said that in the CT and ET groups, from 1 to 10 min when compared with baseline values there was marked elevation in SAP, HR, MAP ($P < 0.01$) and DAP. After insertion of LMA, in MAP, SAP and DAP there was slight increase at 1 min ($P< 0.05$) but no definite increase in HR[47]

In 1999, Kim ES. et al said that there is increase resistance in respiratory system when tracheal intubation is done which by inhaled bronchodilators can be reversed. The authors also mentioned that there is less like chance of LMA causing reversible bronchoconstriction compared to endotracheal tube insertion.[48]

In 2003, Kihara et al documented a study of hemodynamic responses between normotensive and hypertensive patients during intubation and laryngeal mask airway (LMA) insertion. They concluded that in patients receiving LMA there was an attenuated hemodynamic stress response as compared to patients undergoing laryngoscopic intubation.[49]

In 2003, Syed Altaf Bukhari et al study post insertion of laryngeal mask airway was to compare the pressor responses and intraocular pressure changes and tracheal intubation. They concluded that in patients with coronary artery disease and glaucoma where mild changes in hemodynamics and IOP are favoured. LMA could be beneficial..[50]

In 2004 , K. Montazari et al documented a study of hemodynamic response during laryngoscopy and inserting a laryngeal mask airway and came to the conclusion that direct stimulation of the trachea appears to be a major cause of the hemodynamic changes associated with tracheal intubation during general anaesthesia and there were less hemodynamic changes in the patients with LMA insertion.[51]

In 2007 , Naveed Tahir Siddiqui et al said that compared to group II (intubation through the ILMA) group I (direct laryngoscopy) had a higher mean maximum increase in mean arterial pressure, diastolic pressure and systolic pressure. It is may be because of the reason that ILMA causes less mechanical pressure on the pharyngeal structures. The study further stated as conclusion that in patients where noticeable pressor response would be detrimental, intubation with LMA is superior than direct laryngoscopic intubation as it carries less cardiovascular response[52].

M Shafique Tahir et al (2008) did a prospective comparative study to test the conjecture that Laryngeal mask airway is related with lower pressor responses than endotracheal intubation. A statistically notable elevation in heart rate, systolic and diastolic blood pressure was observed after tracheal intubation ($p < 0.05$) . Following laryngeal mask airway insertion, the rise in heart rate was statistically significant ($p<0.05$) while in systolic and diastolic blood pressure there was not much difference in rise. In Endotracheal tube group there was high heart rate than Laryngeal mask airway group and this increase remained significant up to 5 minutes after insertion. It was therefore concluded that endotracheal intubation is associated with marked increase in heart rate, systolic and diastolic blood pressure in comparison to that associated with Laryngeal mask airway. So Laryngeal mask airway can be used in situations where minimal changes in hemodynamics are desirable like in patients with coronary artery disease with no contraindications for using Laryngeal mask airway.[53]

Dipashri Bhattacharya et al(2008) did a randomised controlled study in patients with controlled hypertension to determine the pressor responses following insertion of Laryngeal mask airway as compared to endotracheal intubation. It was observed that tracheal intubation was associated with increase in heart rate from 84 ±7.80 to 86 ± 6.17 ($p<0.05$) and significant increase in systolic blood pressure from 128.60±7.44 to 166.20±8.9 and diastolic blood pressure from 80.70±5.18 to 90.05±2.39($p< 0.01$) as compared to insertion of Laryngeal mask airway. Hence it was inferred that LMA insertion was associated with lesser pressor responses as compared to endotracheal intubation in patients with controlled hypertension. It is an effective method to avoid laryngoscopic pressor responses during endotracheal intubation in hypertensive patients.[54]

In 2010, Seung H Yu et al reported whether in patients undergoing general anesthesia, those provided with a laryngeal mask airway have lower risk of airway related complications than those undergoing endotracheal intubation. Later they came to the conclusion that for patients undergoing general anaesthesia the use of LMA resulted in a statistically and clinically significant lower incidence of laryngospasm during emergence, post-op hoarse voice and coughing than when using an ETT.[55]

In 2011, Elif Bengi Sener et al compared haemodynamic responses and upper airway morbidity following intubating laryngeal mask airway or tracheal intubation via conventional laryngoscopy in hypertensive patients. They came to a conclusion that vigorous and repeated oropharyngeal and tracheal stimulation in hypertensive patients yields greater pressor responses due to LMA intubation than from conventional laryngoscopy.[56]

Ismail SA et al (2011) tested the hypothesis that the effects of insertion of an i-gel supraglottic airway management device on intraocular pressure (IOP) and hemodynamic variables would be milder than those associated with insertion of a laryngeal mask airway (LMA) or an endotracheal tube. It was concluded that insertion of endotracheal tube increased the IOP, Heart rate, Systolic and diastolic blood pressure significantly. These increases were significantly higher than those which followed insertion of i-gel. Thus it was concluded that insertion of the i-gel device provides better stability of IOP and the hemodynamic system compared with the insertion of an endotracheal tube or LMA.[57]

Namita Saraswat et al (2011) did a prospective controlled study to compare in patients undergoing laparoscopic surgeries under General Anaesthesia the efficacy of Proseal laryngeal mask airway and endotracheal tube. It was concluded that properly positioned Proseal laryngeal mask airway proved to be a suitable and safe alternative to Endotracheal tube for airway management in elective fasted, adult patients undergoing laparoscopic surgeries. It provided equally effective pulmonary ventilation without gastric distension, regurgitation and aspiration.[58]

Year 2011 Ayse Mizrak et all conducted a study to compare hemodynamic changes to endotracheal tube, double lumen tube and laryngeal mask airway insertion and came to a conclusion that Mean arterial pressure and HR in Group ETT were significantly higher than in Group LMA at the first minute after tube placement (P = 0.02). He further concluded that there was no variation is MAP or HR values during or after airway placement by LMA. The ETT caused a sudden increase at the first minute after tube placement.[59]

The study conducted by Artaf Waheed et al in 2012 in elderly hypertensive patients undergoing routine surgical procedures was to compare the hemodynamic parameters between ProSeal laryngeal mask airway and endotracheal tube insertion. It concluded that the Increase of heart rate was observed in both the groups but the rise of heart rate in the ETT group was significant at 1 minute, 2 minutes, 3 minutes, and 5 minutes post extubation as compared to PLMA removal ($p < 0.001$). The difference was not significant at 10 minutes after ETT / PLMA removal. MAP also increased significantly in the ETT group as compared to the PLMA group and the rise was also significant at 1 minute, 2 minutes, 3 minutes, 5 minutes, and 10 minutes after extubation as compared to PLMA removal ($p < 0.001$). A rise of RPP was also significantly higher at 1 minute, 2 minutes, 3 minutes, and 5 minutes after extubation as compared to PLMA removal.[60]

In 2012, Maharajan SK compared compare haemodynamic variables and ventilation parameters of I-gel and laryngeal mask airway with tracheal intubation during laparoscopic surgery. Haemodynamic perturbations were maximum with tracheal intubation and moderate with laryngeal mask airway while stable haemodynamics was observed with I-gel. Intra and inter-group comparison revealed significant differences after use of airway devices and after removal as well.[61]

In 2012, Mohsen conducted a study in cases of cataract surgery following anesthesia induction with propofol and remifentanil evaluating intraocular pressure

(IOP) and hemodynamic responses following insertion of laryngeal mask airway (LMA) or endotracheal tube (ETT). There is minimal hemodynamic disturbances in cataract surgery while insertion of LMA or ETT when Propofol is combined with remifentanil, it provides excellent conditions for intubation. Using LMA may be edge over ETT for airway securing in the above said patients as to the fact that LMA insertion is cause less trauma than ETT.[62]

Michele Carron et al in august 2012 suggested that in the case of obese patients without evidence of gastroesophageal reflux and in whom stress activation could be dangerous, PLMA can be considered as a suitable alternative to ETT. Compared with airway management with an ETT, use of PLMA resulted in less hemodynamic and hormonal activation and less hypoxemic and PONV episodes during the postoperative period, during the study of hemodynamic and hormonal stress response to Endotracheal tube and Proseal Laryngeal mask airway for Laparoscopic gastric banding .[63]

O Ajuzieogu et al (2013) to compare the heart rate and blood pressure changes after laryngeal mask airway insertion and endotracheal intubation did a prospective, randomized controlled study. It was concluded that Endotracheal tube insertion resulted in more significant rise of blood pressure. And that Laryngeal mask airway should be used where possible in whom increased stress responses to an insertion of Endotracheal tube may represent a health hazard.[64]

Hosam M Atef et al (2013) did a prospective, randomized controlled comparative study to evaluate the efficacy of Perfusion Index for detecting hemodynamic stress responses to insertion of I-gel, Laryngeal mask airway and endotracheal tube and compare its reliability with the conventional hemodynamic criteria in adults during General Anaesthesia was concluded that perfusion index is second choice to conventional hemodynamic criteria in figuring out stress response while insertion of I-gel , Laryngeal mask airway and Endotracheal tube during propofol fentanyl isoflurane anaesthesia in adult patients.[65]

Year 2015 Hasheem et al concluded In patients specifically those who suffer from ischemic heart disease and are undergoing surgeries; LMA, particularly LMA-S is advocated as a useful airway instrumentation concerning specifically to changes in the heart rate and lesser duration of insertion, it provided supportive hemodynamic changes following insertion of LMA when compared to intubation with ETT in the study.[66]

Rastogi Bhawna et al 2015 despite taking more time than DLS, ILMA offers advantage in attenuating the hemodynamic responses compared to DLS, though numbers of attempts required were more with ILMA as compared to ML. The incidences of postoperative complications were minimal and comparable with both the devices. Hence we conclude that ILMA is a safer alternative to direct laryngoscopy for intubation and offer advantage of being able to provide ventilation until intubation is achieved. The success rate of ILMA overall was similar to that of direct laryngoscopy and intubation.[67]

Sarkar et al 2015 the heart rate increase recorded in the two groups (22.8% in Group I and 22.4% in Group II) was statistically and clinically significant and of equal magnitude. Higher findings of percentage rise in rate pressure product derived in Group I post intubation imply a greater hemodynamic stress and enhanced myocardial oxygen demand following intubation with Direct Laryngoscopy.[68]

According to the study done in 2015 by Saeed Kashani et al, patients in LMA group experienced hemodynamic changes lower than those in combitube group. This is can be an important issue in cardiovascular patients. They further concluded that increased heart rates may cause a threat to the cardiovascular system by decreasing oxygen delivery to the myocardium and intensifying oxygen consumption as well as potential risks of hypertension in patients with cardiovascular diseases. According to this study, LMA insertion is highly recommended in patients undergoing elective surgery, particularly with ischemic heart disease and without risk of aspiration.[69]

A recent study in 2015 was conducted by Kiran I et al to compare hemodynamic response to Laryngeal mask airway and endotracheal tube in hypertensive patients. He said that Although there was a fall in both systolic and diastolic BP after induction in both the groups of our study there was a very highly significant difference ($P < 0.001$) in mean peak increase in heart rate (59.2% in group ET vs 36% in group LMA). It followed a highly significant increase in both systolic and diastolic BP after airway instrumentation in both the groups. However when compared, group ET values were higher compared to LMA group after 1 minute and 3 minutes. The MAP reached maximum value immediately after airway instrumentation. Although, the values of MAP after LMA insertion were significantly lower when compared to tracheal intubation after 1, 3 and 5 minutes. Hence they concluded that where the avoidance of the hemodynamic response is of particular concern use of LMA has edge over tracheal intubation in the anesthetic management of patients.[70]

Thomas Roshith et al 2016 Heart rate increased significantly after the LMA insertion as well as after endotracheal intubation. Significant increase in heart rate was seen till 5 minutes after the procedure. Heart rate increase was much higher in ETT group compared to LMA group. Heart rate returned to baseline at 5 minutes in LMA group and at 10 minutes in ETT group. Systolic, diastolic and mean arterial pressure increased significantly after LMA insertion and endotracheal intubation. Increase in blood pressure was much less in LMA group compared to ETT group. Systolic, diastolic and mean arterial pressure return to baseline early in LMA group compared to ETT group.[71]

In 2017, Jithimul et al conducted a prospective randomized controlled study to compare the hemodynamic response between laryngoscopy and endotracheal intubation and laryngeal mask airway insertion and concluded that laryngoscopy and intubation had more hemodynamic response than insertion of LMA and that its use may be required in the patients in whom a marked pressor response is hazardous. The P value was < 0.05 in all changes of MAP, SBP, DBP, HR.[72]

Suhas Jewalikar et al 2017, concluded from the present study that the mean IOP, heart rate and mean arterial pressure increased after insertion of airway device in both the groups but the rise was significantly greater after ETT intubation at 0 min, 1 min and 3 min after insertion. These parameters were comparable at 5 min after ETT intubation/ LMA insertion. The amplitude and duration of increase in IOP, heart rate and mean arterial pressure was significantly more after endotracheal intubation than LMA insertion. This reflects that stress response to endotracheal intubation is much more than LMA placement.

Thus, LMA is an excellent alternative technique to minimize the increase in IOP and haemodynamic response to tracheal intubation in patients posted for ocular surgeries and in the patients with compromised cardiovascular status.[73]

In a clinical study conducted in 2017 by Balasubramaniam et al it, was observed that during extubation of endotracheal tube and removal of LMA, the heart rate, blood pressure and rate pressure product increased in both the groups. However, the rate of increase was lower in the LMA group. Therefore the study throws light on the advantages in the use of LMA over endotracheal tube, which in the long run would minimize the perioperative morbidity and mortality.[74]

MATERIALS AND METHODS

Study Design: Observational study

Study Setting: Hypertensive patients undergoing elective surgery in OT Complex of Sree Mookambika Institute of Medical Sciences, Kulasekharam.

Duration of study: 12 months

Number of groups studied: two (2)

Detailed Description of the group:

Group A : Group A or ETT Group consists of adult patients with hypertension undergoing elective surgeries not lasting more than 2-3 hours with endotracheal tube after laryngoscopy as a practice to secure airway during general anaesthesia in operation theatre complex of SMIMS, Kulasekharam.

Group B : Group B or LMA Group consists of adult patients with hypertension undergoing elective surgeries not lasting more than 2-3 hours with Laryngeal mask airway insertion without laryngoscopy as a practice to secure airway during general anaesthesia in operation theatre complex of SMIMS, Kulasekharam.

Sample size of each group: 30

Total sample size of the study: 60

Scientific basis of sample size used in the study:

$$\boxed{n = \frac{(Z\alpha + Z\beta)^2(V1 + V2)}{(\mu 1 - \mu 2 - \delta)^2}}$$

Where Z_α=Z value associated with confidence = 1.64

Z_β = Z value associated with power = 0.84

V_1 = variance of mean in Group A = 9.61[18]

(According to Braude et al)

V_2 = variance of mean in Group B = 15.96

μ^1= mean of Group A = 122.7

μ^2= mean of Group B = 126.9

δ = maximum clinical difference acceptable from μ 1 = 2.5

Hence, n = Sample size = 26.8 = 27

We are taking 30 sample size in each group.

Inclusion Criteria:

- Inclusion criteria includes the adult (male/female) patients suffering from hypertension undergoing general anaesthesia (unless contra-indicated) for surgery in Sree Mookambika Institute of Medical Sciences.
- Patients on regular medications for Hypertension as prescribed.
- Patients under Grade 2 of ASA classification.
- Patients giving valid consent.

Exclusion Criteria:-

- Patients unwilling to undergo general anaesthesia for surgery and Intubation.
- Patients with uncontrolled hypertension.
- Patients with active chest infection.
- ASA 3 and ASA 4 patients.

Sixty hypertensive patients with adequate control of BP between the age of 40-60 years of either sex of ASA grade II on oral anti hypertensives were selected for the study. The patients were undergoing elective surgeries lasting for not more than one hour. Exclusion criteria included history of pulmonary, central nervous system or cervical spine disease, difficult intubation, gastro oesophageal reflux and head and neck surgery. Each patient was visited preoperatively when the procedures were explained and informed written consent was obtained. Blood pressure was recorded in the supine position on 3 occasions two hours apart and patients were taken up for the study with systolic BP < 180 mm Hg and diastolic < 110 mm Hg.

Investigations like Hb%, TC, DC, ESR, random blood sugar, serum electrolytes, urine albumin, sugar, chest x-ray and ECG were done. Patients were advised to take oral anti hypertensives as per schedule with the last dose 6 hours prior to surgery. Each patient received pethidine 1 Mg/Kg and phenergan 0.5 Mg/Kg intramuscularly one hour prior to surgery as premedication.

The patients were randomly allotted to one of the two groups (of 30 patients each) group ET and group LMA. The patients in group ET were intubated using macintosh laryngoscope. The patients in group LMA received laryngeal mask insertion. A size 4 macintosh blade with an appropriate size endotracheal tube was used in patients of group ET and size 4 LMA was used in all patients in group LMA.

Intravenous access was established with an 18 G Cannula after arrival in the anaesthetic room. Pulse oxymeter and non-invasive BP apparatus were connected to the patient in the operation theatre. After stabilization period of 5 minutes, the baseline values of heart rate, systolic, diastolic BP and MAP were recorded.

Patients in both groups received preoxygenation via a face mask for 5 minutes. Anaesthesia was induced with thiopentone sodium 5 Mg/Kg I.V and after confirming loss of the eye lash reflex, succinylcholine 2Mg/Kg I.V was given for endotracheal intubation or LMA insertion. After the disappearance of fasciculations, tracheal intubation was performed in group ET and LMA was inserted blindly using the standard technique in group LMA. 2% xylocaine gel was used as a lubricant for both the Endotracheal tube cuff and LMA cuff. Air was injected into the endotracheal tube or LMA cuff as per recommendation.

Anaesthesia was maintained with intermittent positive pressure ventilation using bain's circuit with N_2O 4L/Min and O2 2 L/Min and 2% Sevoflurane.

The values of heart rate, systolic BP, diastolic BP, MAP were recorded after induction, immediately after intubation or insertion and at minute 1, 3 and 5. Rate pressure product which is a product of systolic BP and heart rate was derived at all the intervals.

At the end of five minutes the anesthetic management deferred as per surgical requirements. Any kind of painful stimulus including surgical incision was not allowed while the readings were recorded.

Patients on whom more than one attempt at either intubation or LMA insert ion was tried were excluded from the study, complications like leakage, coughing, gagging, laryngospasm, gastric distension after airway instrumentation did not occur during the study.

All the values were expressed as mean + standard deviation.

Statistical comparison were performed by students paired and unpaired t-test and chi-square test.

P value of >0.05 was considered to be statistically not significant, a value of <0.05 as statistically significant, a P value of <0.01 as statistically highly significant and a P value of <0.001 as statistically very highly significant.

RESULTS

Our study was conducted on 60 patients aged between 40-60 years after obtaining written informed consent. All patients were hypertensives on various types of oral anti hypertensives for different periods of time. Two groups were demonstrated:

Group LMA: Airway of this group patients was secured with Laryngeal mask airway.

Group ET: Patients were intubated with the help of conventional laryngoscopy and Macintosh blade.

Interpretation of results for age

The distribution of age in group ET ranges from 40 to 60 years. The mean age in the group ET was 47.93 years and a SD of 6.017 years. The distribution of age in group LMA ranges from 40 to 60 years. The mean age in the group LMA was 47.57 years and a SD of 6.947 years.

Table 1: Distribution according to age of participants

Age characteristics (years)	Group ET (N=30)	Group LMA (N=30)
Minimum	40	40
Maximum	60	60
Mean	47.93	47.57
Standard deviation	6.017	6.947

Table 2: Interpretation of results for gender

Gender	Group ET		Group LMA	
	Frequency	Percentage	Frequency	Percentage
Male	18	60	21	70
Female	12	40	9	30
Total	30	100	30	100

Figure 21: Distribution of gender in group ET

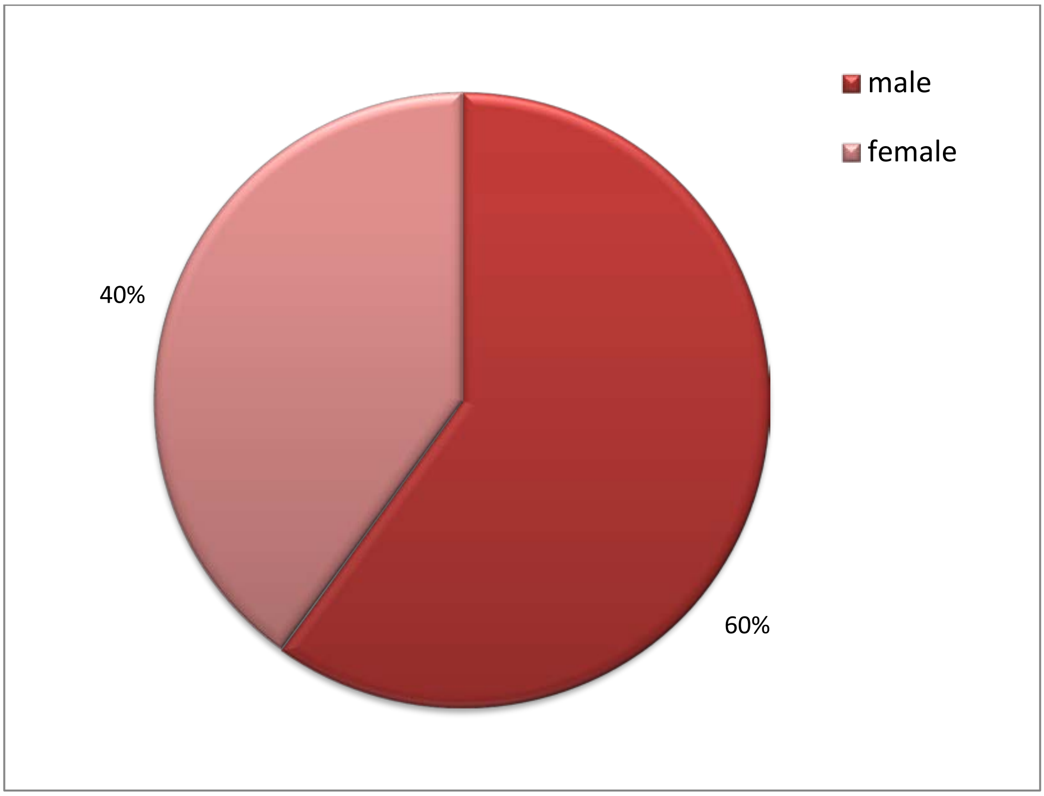
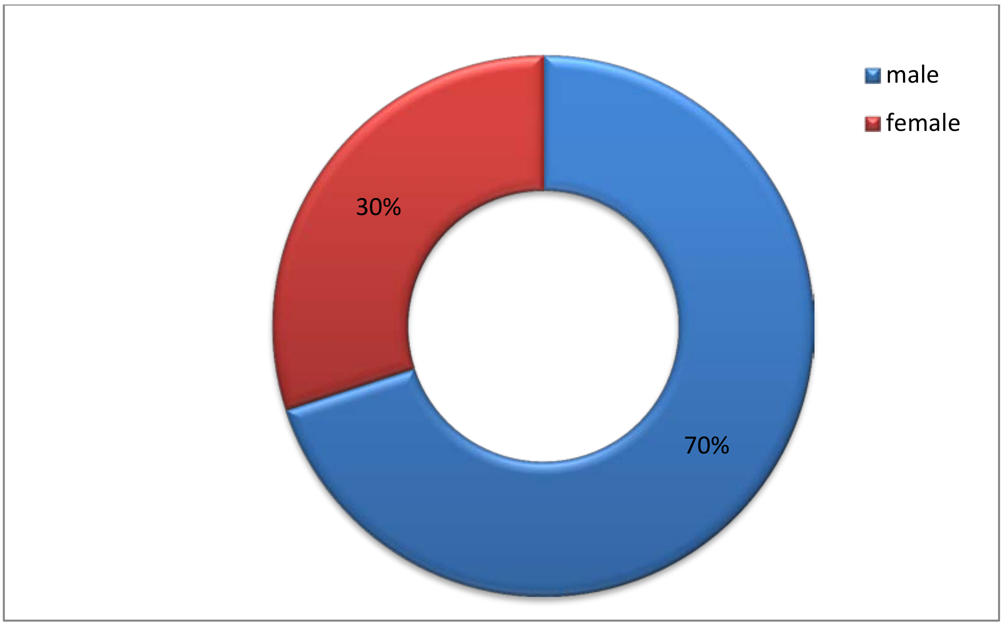


Figure 22: Distribution of gender in group LMA



INTERPRETATION OF RESULTS FOR WEIGHT

The distribution of weight in group ET ranges from 40 to 60 kg. The mean weight in the group ET was 47.93 kg and a SD of 6.017 kg. The distribution of weight in group LMA ranges from 40 to 60 kg. The mean weight in the group LMA was 47.57 kg and a SD of 6.947 kg.

Table 3: Distribution according to age of participants

Weight (kg)	Group ET (N=30)	Group LMA (N=30)
Minimum	41	42
Maximum	60	60
Mean	51.67	51.6
Standard deviation	5.7	6.17

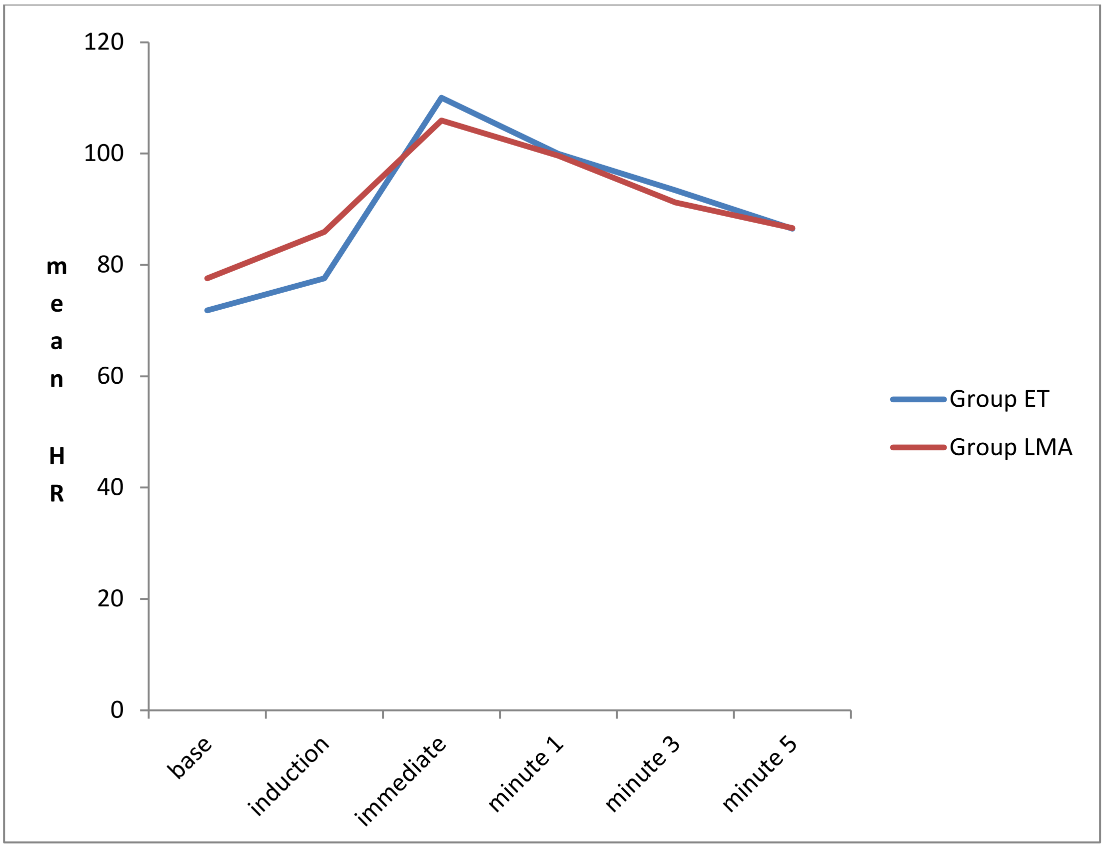
INTERPRETATION OF RESULTS FOR HEART RATE

Table 4 : Comparison of mean heart rate

Time of measurement	Group ET	Group LMA	p value
Baseline	71.8±7.327	77.67±7.836	0.004**
After induction	77.60±6.831	85.90±9.241	0.000***
After intubation			
Immediate	110.03±14.69	105.93±12.53	0.25
60 Seconds	99.93±15.256	99.6±12.21	0.926
180 Seconds	93.40±12.94	91.23±8.74	0.451
300 Seconds	86.57±11.81	86.83±8.73	0.921

***p value of > 0.05

Figure 23: Comparison of mean heart rate



P value of < 0.001 vs baseline is very highly significant

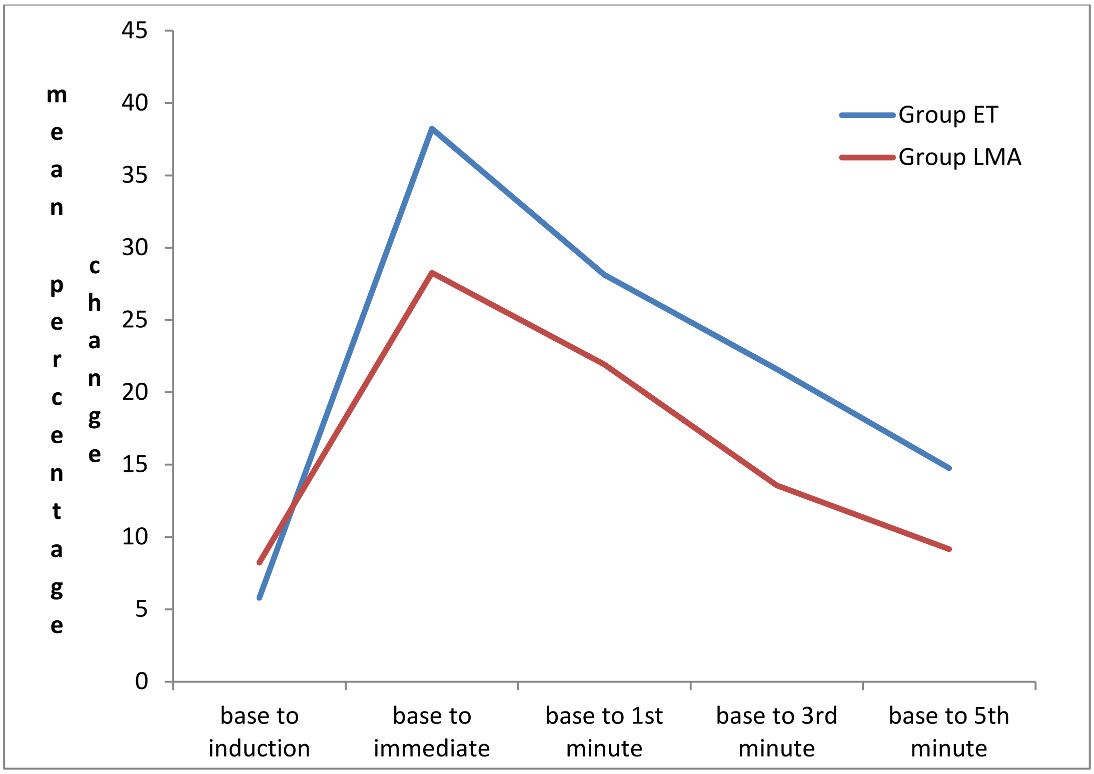
The heart rate increased post induction and remained elevated for more than 3 minutes in both the groups, after LMA insertion and tracheal intubation. The mean increase in heart rate for both the groups were almost similar.

Table 5: PERCENTAGE CHANGE FROM THE BASE LINE – HEART RATE

Time of measurement	Group ET	p value	Group LMA	p value
After induction	5.8±6.69	0.000***	8.23±6.65	0.000***
After intubation				
Immediate	38.23±13.79	0.000***	28.26±11.08	0.000***
60 Seconds	28.13±14.06	0.000***	21.93±9.18	0.000***
180 Seconds	21.6±12	0.000***	13.56±7.93	0.000***
300 Seconds	14.76±11.61	0.000***	9.16±6.85	0.000***

p value < 0.000*** p value - very highly significant.

Figure 24: PERCENTAGE CHANGE FROM THE BASE LINE – HEART RATE



INTERPRETATION OF RESULTS FOR SYSTOLIC BP

Table 6: : Comparison of mean SBP

Time of measurement	Group ET	Group LMA	p value
Baseline	150.63±11.60	142.37±11.56	0.008**
After induction	144.57±11.04	142.37±13.169	0.486
After intubation			
Immediate	190.80±13.67	179.97±19.32	0.015*
60 Seconds	180.07±13.43	173.37±17.51	0.102
180 Seconds	166.03±12.28	154.4±11.09	0.000***
300 Seconds	155.57±10.92	147.87±11.61	0.010*

*P value < 0.05- significant

**P value < 0.01- highly significant

***P value < 0.001-very highly significant

Very highly significant increase in the systolic BP after intubation when compared to insertion of LMA. Also the SBP remained elevated for 1st 3 minutes in both the groups. Hence there was a significant difference in the percentage increase in the SBP between both the groups.

Figure 25: COMPARISON OF MEAN SBP

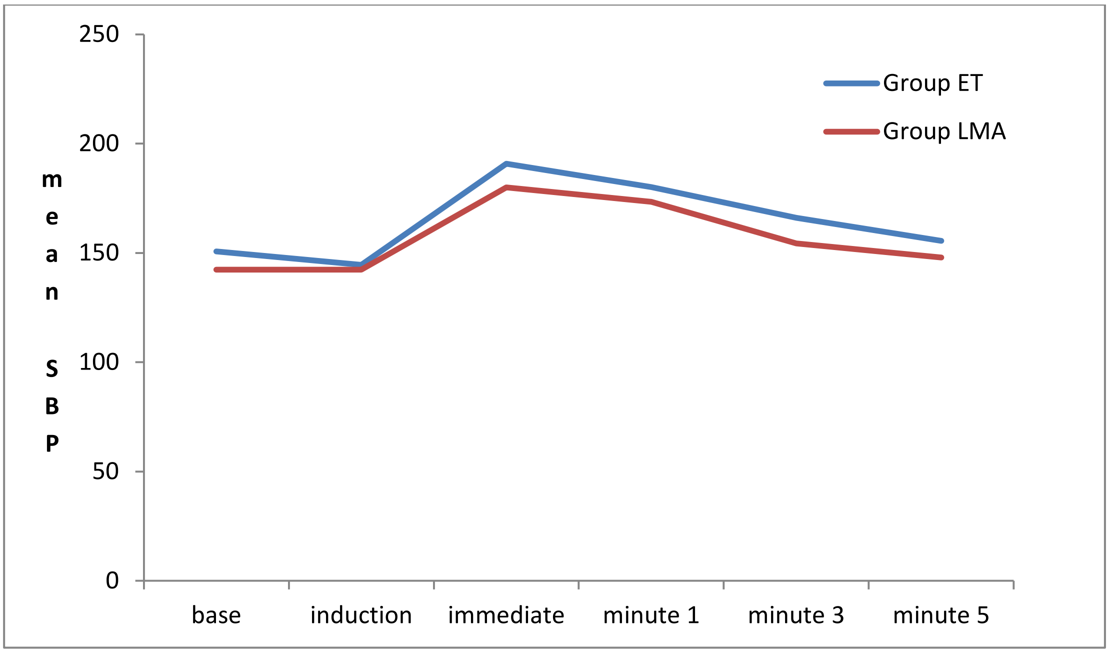


Table 7: PERCENTAGE CHANGE FROM THE BASE LINE – SBP

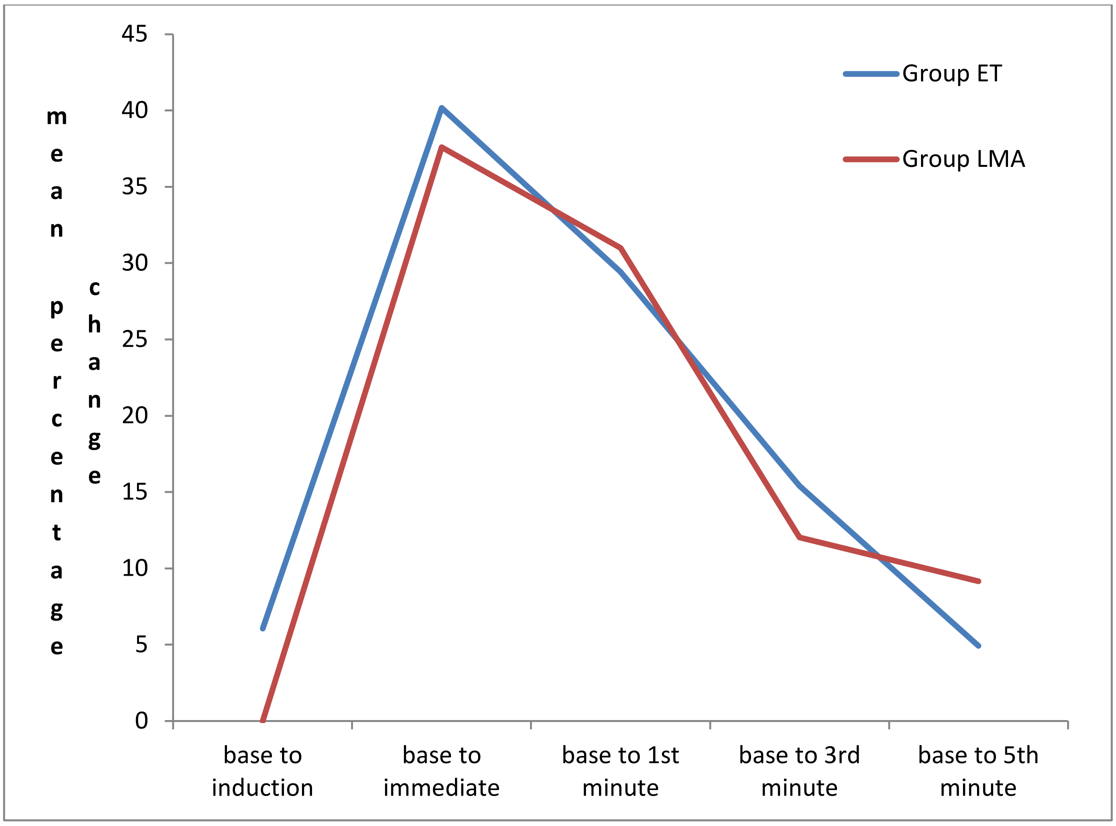
Time of measurement	Group ET	p value	Group LMA	p value
After induction	6.06±9.30	0.001**	0±10.106	1
After intubation				
Immediate	40.167±17.69	0.000***	37.6±21.34	0.000***
60 Seconds	29.433±16.33	0.000***	31±19.12	0.000***
180 Seconds	15.4±12.45	0.000***	12.03±14.7	0.000***
300 Seconds	4.93±10.19	0.013*	5.5±13.49	0.034*

*P value < 0.05- significant

**P value < 0.01- highly significant

***P value < 0.001-very highly significant

Figure 26: PERCENTAGE CHANGE FROM THE BASE LINE – SBP



The percentage change of SBP from the base line was highly significant in Group ET.

INTERPRETATION OF RESULTS FOR DIASTOLIC BP

Table 8: Comparison of mean DBP

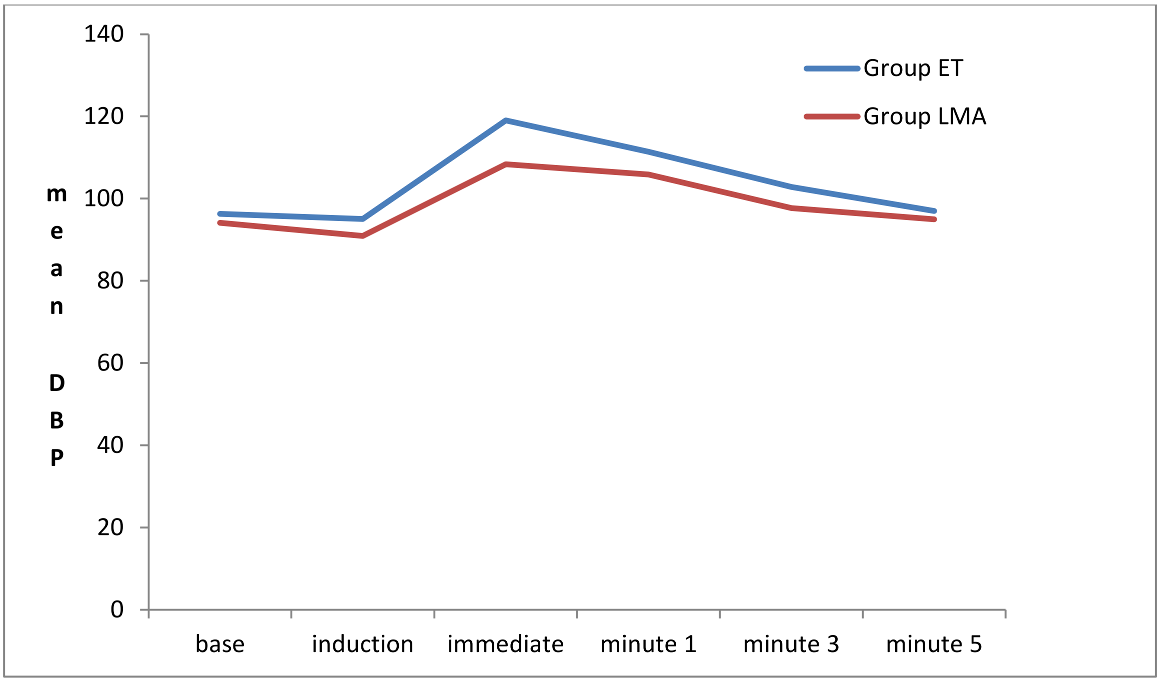
Time of measurement	Group ET	Group LMA	p value
Baseline	96.3±6.32	94.13±7.43	0.229
After induction	95.07±8.41	90.93±9.19	0.074
After intubation			
Immediate	119.03±19.043	108.37±11.18	0.010*
60 Seconds	111.43±18.013	105.90±12.018	0.167
180 Seconds	102.80±8.957	97.67±6.32	0.013*
300 Seconds	97±5.99	94.97±8.389	0.285

*P value < 0.05- significant

**P value < 0.01- highly significant

***P value < 0.001-very highly significant

Figure 27: Comparison of mean DBP



The mean DBP remain elevated for 3 minutes in Group ET and for 1 minute in Group LMA after airway instrumentation. The values for mean increase in the DBP was significantly high in Group ET than Group LMA.

Table 9: PERCENTAGE CHANGE FROM THE BASE LINE – DBP

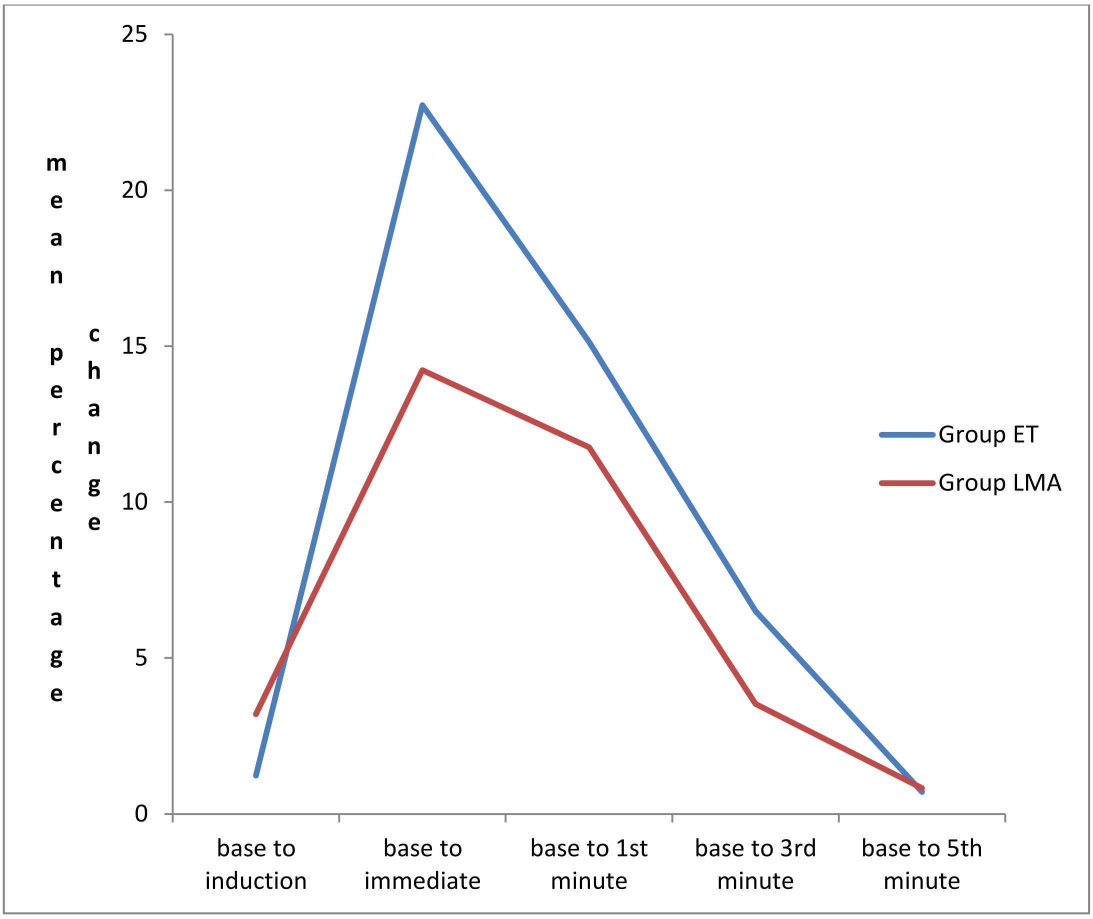
Time of measurement	Group ET	p value	Group LMA	p value
After induction	1.23±8.14	0.413	3.2±5.9	0.006**
After intubation				
Immediate	22.73±20.08	0.000***	14.23±15.4	0.000***
60 Seconds	15.13±18.02	0.000***	11.76±16.09	0.000***
180 Seconds	6.5±10.04	0.001**	3.53±10.16	0.067
300 Seconds	0.7±7.0	0.593	0.83±6.7	0.501

*P value < 0.05- significant

**P value < 0.01- highly significant

***P value < 0.001-very highly significant

Figure 28: PERCENTAGE CHANGE FROM THE BASE LINE – DBP



The percentage change of DBP from baseline was significantly high in Group ET for 1,3,5 minutes whereas for Group LMA, it was comparatively low .

INTERPRETATION OF RESULTS FOR MEAN ARTERIAL PRESSURE

Table 10: Comparison of mean MAP

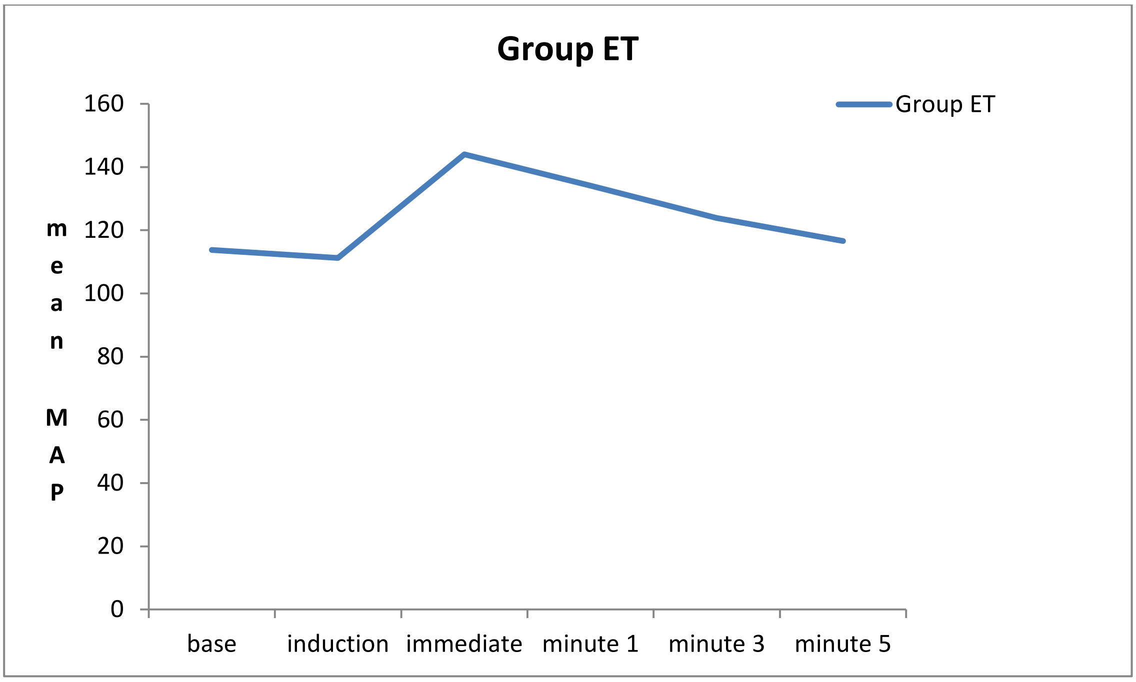
Time of measurement	Group ET	Group LMA	p value
Baseline	113.71±7.55	108.07±8.79	0.010*
After induction	111.2s2±7.39	108.07±9.57	0.159
After intubation			
Immediate	144±15.20	132.54±11.85	0.002**
60 Seconds	134.08±13.73	128.38±11.04	0.082
180 Seconds	123.85±8.55	116.57±6.59	0.000***
300 Seconds	116.59±6.28	112.6±8.24	0.039*

*P value < 0.05- significant

**P value < 0.01- highly significant

***P value < 0.001-very highly significant

Figure 29: Comparison of Mean MAP



The MAP values increased in both the groups after intubation or LMA insertion. The values remained elevated for upto 5 minutes in Group ET and for upto 3 minutes in Group LMA. Group LMA had lower values at all times when compared to Group ET.

Table 11: PERCENTAGE CHANGE FROM THE BASE LINE – MAP

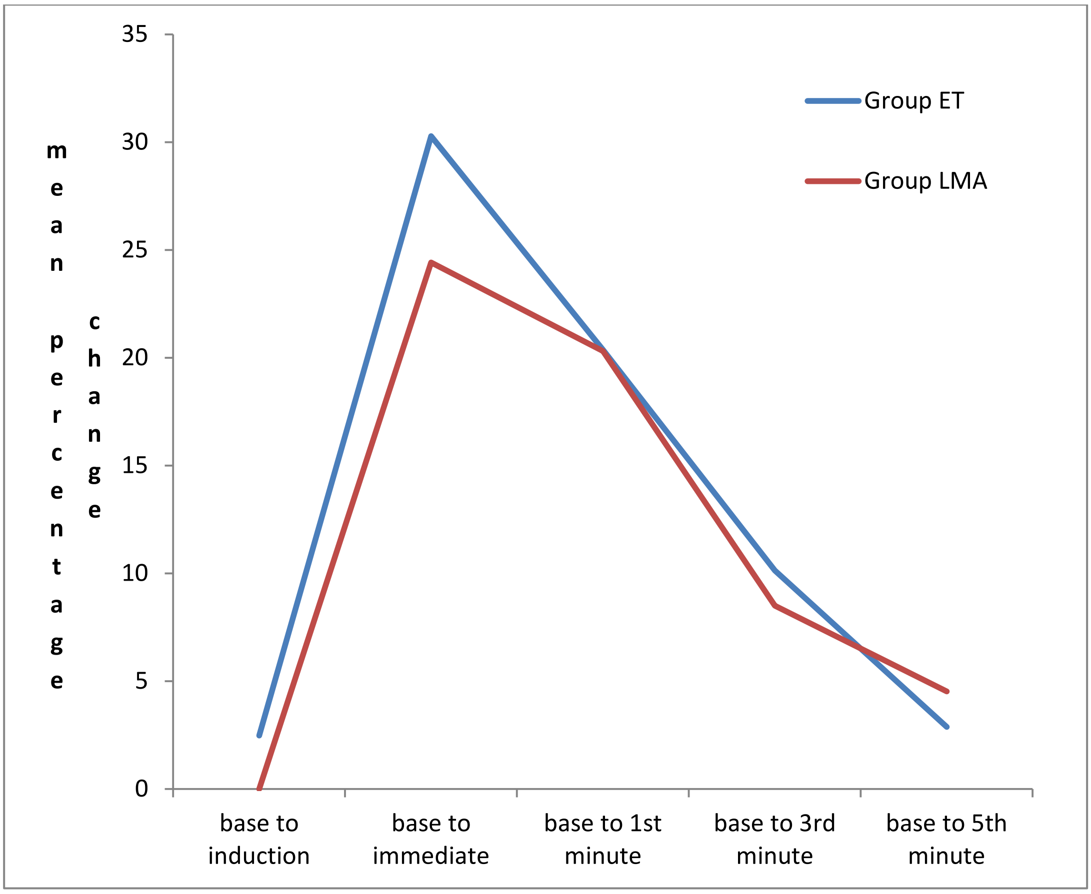
Time of measurement	Group ET	p value	Group LMA	p value
After induction	2.48±7.55	0.082	0±3.36	1
After intubation				
Immediate	30.28±15.53	0.000***	24.41±17.17	0.000***
60 Seconds	20.36±13.63	0.000***	20.31±16.21	0.000***
180 Seconds	10.13±8.44	0.000***	8.5±11.31	0.000***
300 Seconds	2.88±6.38	0.0.02*	4.52±9.14	0.011*

*P value < 0.05- significant

**P value < 0.01- highly significant

***P value < 0.001-very highly significant

Figure 30: Percentage Change from the Base Line – MAP



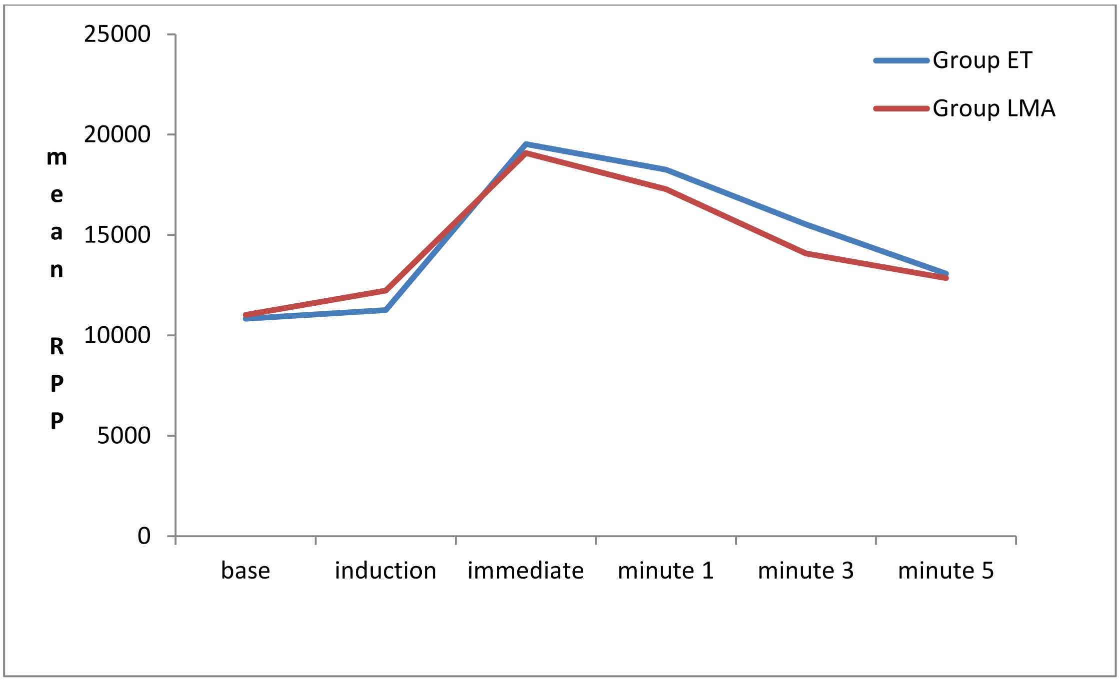
The percentage increase from baseline of mean DBP reached its peak after endotracheal intubation and insertion of LMA. Although values were comparatively higher in Group ET.

INTERPRETATION OF RESULTS FOR RPP

Table 12: Comparison of mean RPP

Time of measurement	Group ET	Group LMA	p value
Baseline	10831.37±1505.883	11030.13±1187.01	0.572
After induction	11268.87±1571.99	12241.57±1806.31	0.030*
After intubation			
Immediate	19532.67±5680.046	19081.80±3141.223	0.705
60 Seconds	18258.57±3524.33	17282.53±2853.24	0.243
180 Seconds	15527.77±2514.42	14088.07±1697.85	0.012*
300 Seconds	13083.13±3207.818	12850.30±1719.99	0.727

Figure 31: COMPARISON OF MEAN RPP



The values of RPP :

After induction: Increased as Heart Rate was seen increasing.

After endotracheal intubation or LMA insertion: Increased due to sympathetic activity

All the values were high for first 3 minutes (P< 0.05), hence significant.

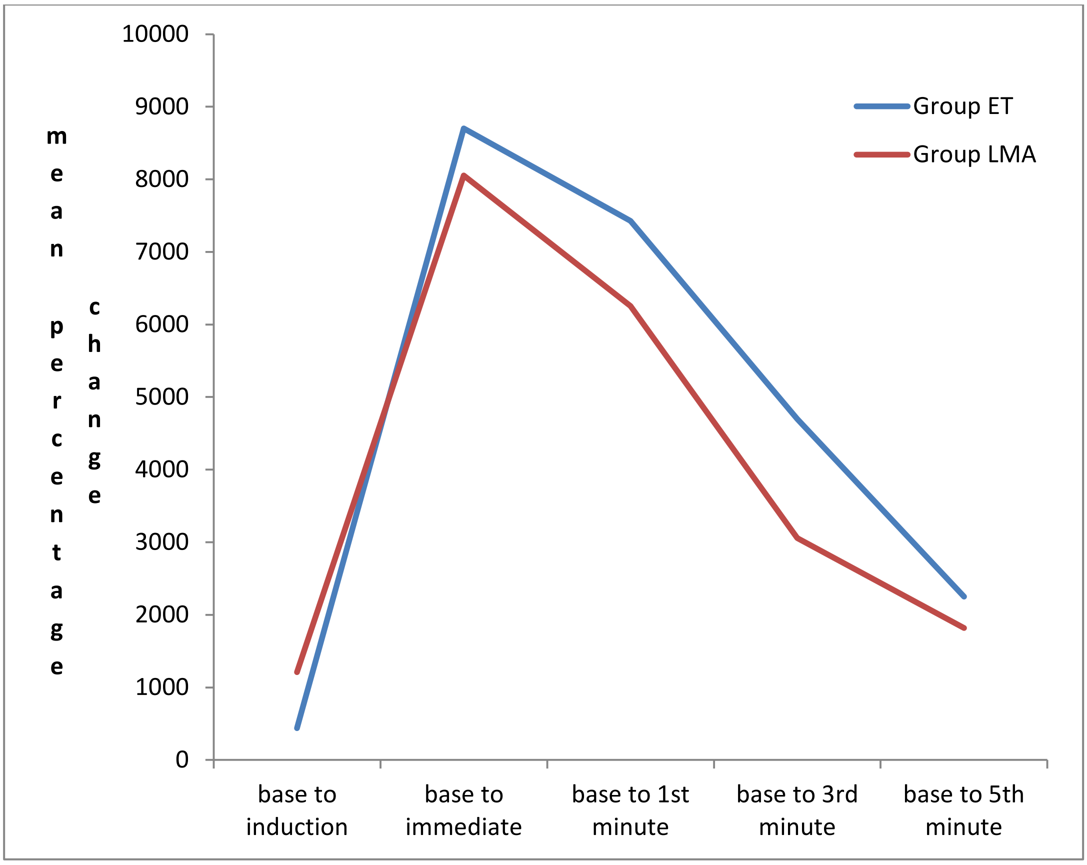
Although the rise of values in Group LMA is far less Group ET.

Table 13: PERCENTAGE CHANGE FROM THE BASE LINE – RPP

Time of measurement	Group ET	p value	Group LMA	p value
After induction	437.5±1395.94	0.097	1211.43±1147.53	0.000***
After intubation				
Immediate	8701.3±5588	0.000***	8051.66±3223.33	0.000***
60 Seconds	7427.2±3177.75	0.000***	6252.4±2747.46	0.000***
180 Seconds	4696.4±1961.31	0.000***	3057.93±1617.97	0.000***
300 Seconds	2251.76±2766.11	0.000***	1820.16±1446.33	0.000***

***P value < 0.001-very highly significant

Figure 32: Percentage change from the base line – RPP



P value of <0.001 which is very highly significant was seen in both the groups. The mean increase in the RPP was higher for Group ET.

DISCUSSION

Airway management by direct laryngoscopy and endotracheal intubation during conduct of general anesthesia induces clinical changes in hemodynamic variables[75].

Tracheal intubation causes variation in concentrations of catecholamine and a reflex rise in sympathetic activity causing hypertension, arrhythmia and tachycardia [76].

Hypertensive patients, patients with Ischaemic heart disease or cerebrovascular disease may be vulnerable to adverse cardiovascular events like Myocardial infarction, CVA or end organ damage due to the significant but short lived hemodynamic effects of laryngoscopy and intubation.[77]

The Laryngeal mask airway belongs to class of supraglottic airway devices that are designed to facilitate positive pressure ventilation and maintain a patent airway while circumventing the disadvantages of an endotracheal intubation like passing through the vocal cords.[18] The situations where LMA is contraindicated are full stomach patients, decreased compliance of the airway and hematological disorders that can increase the chances of bleeding.

Large observational studies have reported high success rates and low complication rates when the LMA was used for airway management during general anesthesia.[78,79]

The study included 60 patients with comparable demographic parameters like weight, gender and age. There was no statistically significant difference in the baseline parameters of HR, SBP, DBP, MAP, RPP between both groups.

In our study post induction, the heart rate increased and again after endotracheal intubation or insertion of LMA. The values remained elevated for up to 5 minutes when compared with the baseline.

From our study we found out that, in both the groups, the mean HR increased to a similar extent. But following LMA insertion, the percentage change from the baseline in HR was 28.26 % as compared to 38.23 % following endotracheal intubation. This difference is statistically significant with a p value < 0.000***. This disparity can be explained by the fact that LMA stimulates both cardiac acceleratory and vagal fibres whereas the cardioacceleratory fibres is much more prominent on endotracheal intubation.

The results were in parallel with Anita and collegues[80] where while inserting LMA there was no significant increase ($P > 0.05$) in mean pulse rate but after intubation with endotracheal tube there was significant increase ($P < 0.05$) in pulse rate which remained high till 1 minute after intubation [9% in Group LMA and 11% in Group ETT].

Although the mean pulse rate returned to baseline value after 3 min which can be attributed to deeper depths of anesthesia achieved with the use of volatile anesthetics until 3 minutes of insertion and intubation.

After induction the systolic and diastolic BP decreased in both our study groups, but airway instrumentation produced a very marked increase in both SBP and DBP following induction in both the groups. These came to40.16% in group ET and by 37.6% in group LMA. As seen from these values, Group LMA has lower increase in SBP and DBP than the ET group. This may be due to decreased total stimulation of afferent fibres in LMA group and ongoing stimulation due to the endotracheal tube present in situ.

Our results were opposite to the study of elif bengi sener[56] and collegues where there was an reduced pattern of response to conventional laryngoscopy and with Intubating laryngeal mask airway [28.9 % in group ETT and 27.2% in group ILMA] and P value was significantly high ($p < 0.05$). The insertion of an ILMA takes much more time than the Conventional laryngoscopy and intubation as it involves three steps –

- Positioning the LMA,
- Intubating through it
- Removing the LMA.

Hence the apnea time and airway manipulation increases to cause a greater hemodynamic response for ILMA.

Similarly a 22.73% and 14.23% increase in diastolic BP was observed in group ET and group LMA respectively, which was significantly higher in Group ET. Our results corresponded to the study conducted by Ali Abdulhamed Mohammed [81] collegues where the rise in diastolic blood pressure was significantly high ($p < 0.05$) {86±4 in ETT Group and 78±7 in LMA Group immediately after insertion}.

Our study was associated with decreased stress response for LMA insertion in comparison with ET tube insertion. This is probably because of the glosso epiglottic fold stimulation during laryngoscopy or insertion of LMA which is considered as a major cause for haemodynamic response. Shribman[4] and colleagues concluded that the tension on the supraglottic tissues caused the sympatho-adrenal response. But in LMA Group, this lateral pressure on the pharyngeal mucosa by the LMA cuff was transient and when the mask was in situ, there was only a decreased pressure transmission as explained by Marjot[36] et al.

There was an increase in MAP value after both LMA insertion and laryngoscopy with intubation. Group LMA showed markedly lesser increase in MAP values than Group ETT which was like the other hemodynamic parameters.

Our study results were in co-ordination with the study conducted by Jindal[82] puja et all, Laryngoscopy and intubation were accompanied by a rise in MAP that remained above pre insertion levels even by 5 min. LMA insertion in contrast was associated with rise in MAP that fell to pre insertion values after 1st min (20.59% increase over the basal value in group ETT and 2.31% over basal value Group LMA) ($P < 0.05$).

The RPP values also increased as a result of airway stimulation in both the groups. The RPP values in group ET reached a mean peak increase of 19532.67, corresponding mean peak increase in group LMA was 19081.80.

In a study conducted by Jayita Sarkar[68] and collegues to differentiate between Hemodynamic response to endotracheal intubation using C-Trach assembly and direct laryngoscopy, they found that the rise in rate pressure product from basal value at all-time intervals was consistently higher in Group ETT as compared to Group LMA- C TRACH.

Apart from the individual patient's responses and discrepancies in the number of patients studied the other possible explanation for the differences among the study results could be because the patients were on different groups of antihypertensive drugs and were treated for variable duration. The observations of our study were not plotted beyond 5 minutes because of the possible return of neuromuscular conduction. Even though the intervals selected to record the haemodynamic response were closely related with the maximum changes that could occur after stimulation of airway, the absence of continuous monitoring in our study might have a role in altering the results.

From this study we infer that in situations where intubation pressor response is desirably avoided as in hypertensive patients and so LMA should be preffered for selected surgeries.

CONCLUSION

Our study concludes that, insertion of the laryngeal mask airway causes lesser haemodynamic response than tracheal intubation in hypertensive patients.

SUMMARY

Hypertensive patients are at an increased risk of adverse cardiovascular events due to the stress response of laryngoscopy and intubation.

This can be attenuated to an extent by the use of an LMA, which provides positive pressure ventilation and a patent airway for selected surgeries.

Our study examined the difference between the degree of stress response to intubation as compared to LMA insertion in hypertensive patients.

Hence we infer the following:

- A very highly significant difference in maximum increase in heart rate from baseline between the two groups.
- LMA insertion also causes some stress response but to lesser degree as compared to endotracheal intubation.
- Notable variations of values between the two groups in systolic B.P, diastolic B.P, Mean Arterial Pressure and Rate Pressure Product after immediate insertion of LMA or ET.

Therefore, in hypertensive patients it is advisable to avoid endotracheal intubation and maintain the airway with an LMA, so as to attenuate stress response.

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INSTITUTIONAL HUMAN ETHICS COMMITTEE

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES,
KULASEKHARAM, TAMILNADU

Communication of Decision of the Institutional Human Ethics Committee(IHEC)

SMIMS/IHEC No: 1 /Protocol no: 41 / 2016

Protocol title: A COMPARATIVE STUDY OF HEMODYNAMIC RESPONSE WITH LARYNGOSCOPIC ENDOTRACHEAL INTUBATION AND LARYNGEAL MASK AIRWAY INSERTION IN HYPERTENSIVE PATIENTS AT TERTIARY CARE HOSPITAL
Principal Investigator: Dr.Shrey Sharma
Name& Address of Institution: Department of Anaesthesiology Sree Mookambika Institute of Medical Sciences, Kulasekharam ☑ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): 15.12.2016 Date of previous review , if revised application:
Decision of the IHEC: ☑ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of : eighteen months

Please note*

- Inform IHEC immediately in case of any Adverse events and Serious adverse events.
- Inform IHEC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above. Annual report to be submitted to IHEC.
- Members of IHEC have right to monitor the trial with prior intimation.

Reneegalyangadhar

Signature of Member Secretary IHEC

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES * KULASEKHARAM *
IHEC
Date 21/12/16

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

KULASEKHARAM

RESEARCH COMMITTEE

CERTIFICATE

This is to certify that The Research Protocol Submitted by SHREY SHARMA *Faculty / Post Graduate from Department of* ANAESTHESIOLOGY *Titled* A COMPARATIVE STUDY OF HAEMODYNAMIC RESPONSE WITH LARYNGOSCOPIC ENDOTRACHEAL INTUBATION AND LARYNGEAL MASK AIRWAY INSERTION IN HYPERTENSIVE PATIENTS. *is approved by the Research Committee.*

Chair Person

Prof. & H.O.D.
Dept. of Bio-Chemistry
Sree Mookambika Institute of Medical Sciences
Kulasekharam 629 161

Convenor

Prof. & H.O.D.
Dept. of Physiology
Sree Mookambika Institute of Medical Sciences
Kulasekharam 629 161

Date :

PROFORMA FOR ANAESTHESIA RECORD

PRE-ANAESTHETIC EVALUATION

ID No: **Date:**

Age : .... (in years) **I.P No:**

Address:

History From: Patient**[ ]** Guardian**[ ]**

Surgical Diagnosis:

Proposed Surgery:

Previous anaesthesia and relevant history:

Relevant past history:

(Respiratory/Cardiovascular/Hepato/Gastrointestinal/Neuro/Musculoskeletal/Renal/Others if any)

Current medications (if any):

Any other significant history?

Known Allergies(to drugs/medications):

General Physical Examination: (Good/Fair/Sick/Conscious/Drowsy/Unconscious)

Pulse rate: /min Blood Pressure: /mmhg Pallor:

Cyanosis: Temperature: Edema:

Height (cms): Weight (kgs):

Airway:

M.P : T-M distance: M-O distance:

Neck Movements: full/limited/none

Teeth: (poor/loose)

Micrognathia: Short muscular neck:

Morbid Obesity: Others :

Examination Findings:

Pulmonary Examination: (smoker/not)

Cardiovascular Examination:

Abdominal Examination: (alcoholic/not)

Neuro-muscular Examination:

ECG:

X-ray Chest:

ECHO/TMT/Others:

INVESTIGATIONS AND LABORATORY REPORTS :

Hemoglobin:	gm/dL	LFT:	
TC:	cell/cumm	Serum Bilurubin:	mg/dL
DC:	%/L	Direct Bilurubin:	mg/dL
ESR:	mm/L	Indirect Bilurubin:	mg/dL

Blood Sugar:

Fasting : mg/dL SGOT: IU/L

Post-prandial : mg/dL SGPT: IU/L

Random : mg/dL SAP: IU/L

Blood Urea : mg/dL S. Protein: gm/dL

Serum Creatinine : mg/dL Total Protein: gm/dL

Blood Group and Rh factor: Albumin Globulin ratio:

Urine Routine: BT: .....min.......sec

CT: .....min........sec

Serology: [ ] HIV [ ] HBSAG Others :

ASA Physical Status: 1 2 3 4 5 6 E

Patient accepted for Anaesthesia: Yes **[ ]** No **[ ]**

Planned Anaesthesia Technique:

Pre-medications and Instructions:

Name of the Anaesthesiologist: Signature :

CASE RECORD FORM

ID No: .... **Date: ....**

Age: .... years **Sex: M [ ] F [ ]**

I.P No:

Anaesthesiologist: **Surgeon:**

Procedure: **Position:**

Pre-procedure:

Consent signed: Yes **[ ]** No **[ ]** **Chart Reviewed:**

NPO since: .... hours **Full stomach:** Yes **[ ]** No **[ ]**

Patient reassessed prior to anaesthesia:

Pre-anaesthetic state: (Awake/calm/anxious/uncooperative/sedated/unconscious)

Pre-procedure vitals:

Pulse rate: ..../min **Blood Pressure: .... mm/Hg**

Respiratory rate: ..../min **Temperature: ....°F**

SpO_2: ....%

Anaesthesia machine checked:

Eye care: Yes **[ ]** No **[ ]**

Pressure points checked and padded: Yes **[ ]** No **[ ]**

Clinical Alarms checked & activated: Yes **[ ]** No **[ ]**

MONITORS AND EQUIPMENT:

Non-invasive B.P: ☐ Continuous ECG: ☐ Pulse Oximeter: ☐

ANAESTHETIC TECHNIQUE:

GA induction

ET tube size and LMA Size

Intravenous	☐	Pre Oxygenation	☐	RSI	☐
Inhalational	☐	IM	☐	Cricoid pressure	☐

IV induction agent **Dose**
Inhalational agent **Concentration**
Muscle relaxation for intubation **Dose**
Others

GA maintenance

☐ Inhalational ☐ Inhalational/IV

IV fluids

Medications used intraoperatively:

Urine output:

Intraoperative Vitals monitoring:

Symbols used: B.P: Systolic: Diastolic:
MAP: Pulse rate:
Respiratory rate:
RPP (rate pressure product)

Post-op status:

Awake ☐ Stable ☐ Drowsy ☐ Unconscious ☐ Intubated ☐ Unstable ☐

Pulse : ..../min BP: ....mm/Hg SpO2: ......% Temp: ....°F
Patient transfer : Recovery room/ ICU/HDU

Signature of Anaesthesiologist

INFORMED CONSENT DOCUMENT (ICD)
PATIENT/PARTICIPANT INFORMATION SHEET
INFORMATION FOR PARTICIPANTS OF THE STUDY

1. **Title of the study:** A comparative study of haemodynamic response with laryngoscopic endotracheal intubation and laryngeal mask airway insertion in hypertensive patients at Tertiary care Hospital.

2. **Name of the Principal Investigator:** Dr. Shrey Sharma
Postgraduate – M.D Anaesthesia
Sree Mookambika Institute of Medical Sciences
Kulasekharam

Name of the Guide: Dr. S. Somasundaram
Professor
Department of Anaesthesiology
Sree Mookambika Institute of Medical Sciences
Kulasekharam

Name of the Co-Guide : Dr.Beula G
Asst. Professor
Department of Anaesthesiology
Sree Mookambika Institute of Medical Sciences

3. **Purpose of the study:**

The hemodynamic response, manifesting as increase in heart rate and blood pressure are due to reflex sympatho-adrenal discharge provoked by epi-laryngeal and laryngo- tracheal stimulation subsequent to laryngoscopy and tracheal intubation. Deleterious hemodynamic consequences in the form of increased heart rate, exaggerated hypertension, increased work load to heart and hypoxia following laryngoscopy and endotracheal intubation is matter of concern particularly in patients with hypertension and ischaemic heart disease.

4. Procedure/ methods of the study

After acceptation of the thesis by the research and ethics committee, an informed written consent will be obtained from all patients with hypertension undergoing surgery in

Sree Mookambika Institute of Medical Sciences, Kulasekharam. Blood Pressure should be recorded in the supine position on 3 occasions two hours apart and patients were taken up for the study with systolic ≤ 140 mm hg and diastolic ≤ 90 mm hg. Patient will be started on with 500mL of RL through 18G cannula under asepsis , premedication will be given with Inj. Ranitidine 50mg i.v, Inj. Metoclopramide 10mg slow i.v and the Multiparameter monitors will be attached and the heart rate, blood pressure and oxygen saturation will be constantly recorded from the time of administration of premedication till the end of surgery. After positioning the patients in operation theatre, Group A shall be intubated with Endotracheal Tube of different sizes after visualizing the vocal cords with laryngoscopy and Group B shall be blindly intubated with laryngeal mask airway (LMA). Mean arterial pressure, Systolic Blood Pressure, Diastolic Blood Pressure, Rate pressure product shall be recorded intra- op.

5. Expected duration of theParticipant's participation in the study:

Throughout the surgery.

6. Expected Benefits of the Research for the participants:

The use of Laryngeal mask airway in patients with hypertension can reduce the post- op Complications.

7. Expected risk of the participants: Transient Tachycardia and Transient Hypertension

8. Maintenance of confidentiality of records: All data collected for the study will be kept confidentially. No personal details will be revealed.

9. Provision of free treatment for research related injury:- Yes

10. Compensation for participating in the study:- No

11. Compensation to the participants for forseable risks and unforeseeable risks related to research study leading to disability or death:- If at all occurs hospital shall provide

12. Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled:- Yes

13. **Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes, or would be shared with others, this should be mentioned:-** Yes

14. **Address and mobile number of the principal investigator(PI):-**

Dr. Shrey Sharma
Post Graduate – M.D Anaesthesia
Department of Anaesthesiology
Sree Mookambika Institute of Medical Sciences,
Kulasekharam
Mobile number: 08557826461
e-mail: sharmashrey2@gmail.com

CONSENT FORM

TITLE OF THE PROJECT: A comparative study of haemodynamic response with laryngoscopic endotracheal intubation and laryngeal mask airway insertion in hypertensive patients at Tertiary care Hospital.

PARTICIPANTS NAME:

ADDRESS:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I understood the above study and had the opportunity to ask questions, I understand that my participation in this study is voluntary and that I am free to withdraw at any time. Withdraw at any time, without giving any reason, without the medical care that will be normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose. I have been given an information sheet giving details of this study. I fully consent to participate in the above study.

(I also consent/ do not consent to use my stored biological samples for future scientific purposes: Yes/No – if Applicable)

Signature of the Participant: __________________________ Date:______________

Signature of Witness:________________________________ Date:______________

Name and Address of Witness:

Signature of the Investigator:__________________________ Date: _____________

Sl. No	IP No.	Age (Years)	Sex	Wt. (Kgs)	Type of surgery	HR						
						Baseline	Post Induction	Post Intubation				Baseline
								Immediate	1 (min.)	3 (min.)	5 (min.)	
1.	127399	60	F	45	Fractional Currettage	72	76	100	80	80	80	130
2.	127611	60	F	52	Fractional Currettage	75	80	110	100	100	80	150
3.	135738	47	M	55	Inguinal Hernia Repair	75	73	140	143	90	85	145
4.	136992	58	F	50	Skin Grafting Foot	82	76	138	122	110	90	160
5.	145006	50	F	52	Wound Debridement Leg	90	85	135	124	113	110	160
6.	149293	52	M	56	Inguinal Hernia Repair	72	76	100	95	90	90	150
7.	149901	50	M	59	Wound Debridement Leg	85	93	110	100	90	85	165
8.	152201	42	F	46	Ulnar Nerve Decompression	63	74	110	108	106	90	189
9.	152180	50	F	42	Ext. Fixator Removal Hand	72	75	102	90	89	80	140
10.	156135	48	F	54	I & D Leg	76	85	100	95	92	90	150
11.	165369	42	F	49	Wound Debridement Leg	72	79	100	95	90	89	152
12.	166959	50	M	57	Wound Debridement Leg	60	68	78	68	60	55	140
13.	167357	52	F	50	URS	60	75	110	90	80	82	135
14.	166792	45	M	45	I & D Hand	70	73	110	100	103	100	150
15.	168147	50	M	53	I & D Calf Abscess	75	84	107	95	93	89	142
16.	160792	42	M	50	Sebaceous cyst Excision	75	85	110	89	90	85	150
17.	167678	40	F	52	URS	74	81	120	115	110	90	140
18.	167678	56	M	60	I & D Leg	70	89	110	89	78	76	160
19.	168441	40	M	50	I & D Leg	65	76	114	97	90	85	150
20.	168450	42	F	42	Neuroma Excision Wrist	73	86	109	102	100	85	150
21.	168698	42	M	56	I & D Ankle	76	73	85	79	75	70	160
22.	168698	46	M	59	Cystoscopy	70	74	135	114	110	112	156
23.	168977	47	M	60	Cyst Excision Foot	65	76	112	108	102	90	130
24.	168997	41	M	48	Haemorrhoidectomy	78	65	90	85	81	70	150
25.	168965	50	M	41	Implant Removal Leg	58	63	104	91	86	81	150
26.	169176	58	M	59	I & D Abdominal Wall Abscess	76	81	114	109	110	90	156
27.	169227	42	M	60	I & D Index Finger	68	75	113	109	85	80	140
28.	166796	45	M	46	Haemorroidectomy	73	75	130	112	110	108	160
29.	169322	43	M	52	Haemorroidectomy	74	85	110	108	106	100	150
30.	173120	48	F	50	Nail Removal Index Finger	60	72	95	86	83	80	159

SBP					DBP						MAP		
Post Induction	Post Intubation				Baseline	Post Induction	Post Intubation				Baseline	P ost Induction	
	Immediate	1 (min.)	3 (min.)	5 (min.)			Immediate	1 (min.)	3 (min.)	5 (min.)			Immediate
138	179	160	158	142	90	90	110	94	93	90	103.33	106	133.00
150	160	155	155	150	90	90	100	100	100	90	110	107	120.00
140	180	170	170	165	90	90	150	132	116	96	108.33	106.60	160.00
150	200	190	180	180	90	90	120	100	100	95	113.33	110	146.00
150	210	180	180	170	90	120	130	130	115	110	113	130	183.30
145	180	170	150	150	90	90	110	100	90	90	110.00	108.30	133
150	198	190	180	160	90	90	150	130	120	100	115	110	166.00
160	190	185	178	165	108	100	118	125	120	115	135.00	116.60	142.00
132	220	200	170	155	90	90	110	110	100	95	106.66	104	146.60
145	180	160	160	150	90	90	160	130	120	100	110	108	166.60
141	190	184	170	167	100	95	115	112	110	104	117.33	111.00	140.00
133	174	160	145	140	90	86	114	109	90	92	106.66	101.66	134
130	195	180	158	144	105	100	110	110	102	102	115	110	138.30
147	195	183	171	160	92	90	120	97	98	96	111.33	107	145.00
140	186	172	171	160	90	90	100	98	98	95	107.33	106.66	129
145	180	170	162	148	90	92	90	90	94	90	90	109	120
140	194	185	172	160	100	90	110	110	100	100	113.33	106.66	138
186	200	190	186	170	100	100	130	114	110	90	120	128.60	153
147	190	190	188	160	100	94	110	100	94	90	116.66	111.33	136.66
130	210	180	155	138	100	100	100	106	100	98	116.00	110	136.60
152	200	200	182	170	104	123	110	100	96	98	122.66	132.60	146.00
150	190	170	163	160	100	100	110	100	100	100	118.66	116.66	136.66
128	210	200	138	130	100	92	150	180	100	90	110	104	170
136	190	180	163	152	100	98	98	100	98	100	116.66	110.66	128.60
146	182	180	160	152	100	90	150	100	98	92	117	108.66	160.60
150	185	190	166	160	100	100	110	110	108	100	118.66	116.66	135.00
136	200	198	178	148	110	100	130	126	116	96	120.00	112.00	153.30
150	210	200	160	152	90	90	106	100	100	98	113.33	110	140.66
150	178	165	160	158	100	92	100	100	98	100	117	111.33	126
140	168	165	152	151	100	90	150	130	100	98	119.66	106.66	156

			RPP							
POST INTUBATION			Baseline	Post Induction	POST INTUBATION			
1 (min.)	3 (min.)	5 (min.)			Immediate	1 (min.)	3 (min.)	5 (min.)
116	114.60	107.60	9360	10488	17900	12800	12640	11360
118	118	110.00	11250	12300	17600	15500	15500	12000
145	134.00	119.00	10875	10220	25200	24310	15300	14025
130.00	127	123.30	13120	11400	27600	26220	19800	14850
146.66	137	130.00	14400	12750	28350	24300	20340	19800
123	110.00	110.00	10800	11020	18000	16150	13560	13500
150.00	140	120	14025	13950	21780	19000	16200	13600
145	139	131.60	11907	11840	20900	19980	18868	14850
133.30	123.33	115	10080	9900	22440	18000	15130	12400
140.00	133.30	117	11400	12325	18000	15200	14726	13500
136	130.00	125	10944	11139	19000	17480	15300	14863
126.33	108.30	108.00	8400	9044	13572	10880	8700	7700
133	120.60	116	8100	9750	21450	16200	12640	11808
125.66	122.33	117	10500	10731	21450	20130	17613	16000
122.66	122	116.60	10650	11760	19902	16340	15903	14240
116.66	116.66	109.30	11250	12325	19800	15130	14580	12580
135.00	124	120	10360	11340	2328	21275	18920	14400
139.33	135.33	116.60	11200	16554	22000	16910	14508	12920
130	125.30	116.60	9750	11172	21660	18430	16920	1360
130.66	118.30	111.33	10950	11180	22890	18360	15500	11730
133	124.66	122.00	12160	11096	17000	15800	13650	11900
123.33	121	120	10920	11100	25650	19380	17930	17920
186.60	113	103	8450	9728	23520	21600	14076	11700
126.66	119.60	117.33	11700	8840	17100	15300	13203	10640
126.66	118.66	112	8700	9198	18928	16380	13760	12312
136.66	127.33	120.00	11850	12636	21090	20710	18260	14400
150	136.60	113.30	9520	10200	22600	21582	15130	11840
133.33	120	116	11680	11250	2730	22400	17600	16416
121.60	118.66	119	11100	12750	19580	17820	16960	15800
142	117.30	115.60	9540	10080	15960	14190	12616	12080

Sl. No	IP No.	Age (Years)	Sex	Wt. (Kgs)	Type of surgery	HR						SBP						
						B as eline	P ost Indu ction	Post Insertion				B as eline	P ost Indu ction	Post Insertion				B as eline
								Immediate	1 (min.)	3 (min.)	5 (min.)			Immediate	1 (min.)	3 (min.)	5 (min.)	
1	126872	60	M	50	Cystolithopexy	80	90	115	110	96	90	155	157	170	170	160	160	100
2	131380	41	F	45	Haemorrhoidectomy	70	80	120	100	100	90	145	150	170	160	155	150	90
3	131991	41	M	60	Disarticulation of Digit of Leg	80	80	112	110	100	90	160	160	165	170	150	140	100
4	131242	46	M	56	URS	98	100	128	122	100	98	108	110	190	185	169	150	71
5	130218	47	M	50	Skin Grafting Foot	90	100	125	130	104	94	125	135	184	155	147	130	90
6	133396	40	F	45	Lithotripsy	80	90	125	100	100	100	140	150	175	170	150	160	90
7	133321	41	M	47	Inguinal Hernioplasty	80	84	130	120	100	92	130	150	172	165	160	140	90
8	134602	55	M	52	Wound Debridement Leg	90	90	110	100	90	90	140	150	156	150	134	140	90
9	136629	40	F	45	Cystoscopy	62	64	102	86	80	70	140	133	200	180	150	130	83
10	137777	60	M	43	Inguinal Hernia Repair	88	90	115	112	100	100	150	165	210	200	150	160	100
11	138395	50	F	50	Ganglion Excision Foot	80	96	100	96	90	90	140	158	180	170	160	150	100
12	138335	42	M	60	Circumcision	75	80	92	86	80	80	130	108	190	186	169	170	90
13	139307	60	M	60	I & D Abdominal Wall Abscess	76	90	108	105	106	92	150	130	220	210	160	160	100
14	141057	48	M	60	URS	82	80	110	100	84	80	140	140	165	160	136	134	100
15	140914	40	M	54	URS	72	86	109	96	90	80	130	132	160	160	140	140	100
16	141756	40	M	50	URS	80	90	100	100	96	94	150	140	160	150	140	140	100
17	145014	52	M	45	Haemorrhoidectomy	75	95	112	110	100	100	150	150	192	190	160	150	106
18	146097	60	M	57	I & D Gluteal Abscess	80	82	96	99	86	80	140	140	176	170	160	150	90
19	147019	52	F	60	Haemorrhoidectomy	70	72	92	86	75	70	136	140	208	200	160	152	94
20	144884	57	M	58	Skin Grafting Leg	82	95	94	90	90	90	145	152	165	160	155	154	100
21	146084	50	F	58	Haemorrhoidectomy	71	93	110	107	90	87	140	133	210	200	152	135	83
22	147723	50	M	60	I & D Perianal Abscess	84	90	100	100	96	92	140	148	150	148	145	127	99
23	166888	42	F	45	URS	70	85	100	92	90	90	160	150	200	180	160	162	100
24	159310	42	M	52	Skin Grafting Leg	80	100	120	110	100	90	155	140	196	194	170	150	100
25	167654	43	M	56	I & D Ischiorectal Abscess	64	74	95	85	80	70	140	132	165	160	150	156	90
26	167904	52	M	49	I & D Perianal Abscess	70	76	86	85	80	80	162	156	198	192	180	170	88
27	167991	40	M	50	Haemorrhoidectomy	80	95	98	95	90	90	150	150	190	186	168	156	90
28	169165	43	M	44	Wide Excision Leg Ulcer	76	80	85	82	82	76	140	138	170	170	160	140	90
29	169436	48	F	42	Cystoscopy	70	72	95	89	82	80	130	130	162	160	140	140	100
30	169384	45	F	45	Wound Debridement Leg	75	78	94	85	80	80	150	144	150	150	142	140	100

DBP					MAP						RPP					
Post Induction	Post Induction				Baseline	Post Induction	Post Insertion				Baseline	Post Induction	Post Insertion			
	Immediate	1 (min.)	3 (min.)	5 (min.)			Immediate	1 (min.)	3 (min.)	5 (min.)			Immediate	1 (min.)	3 (min.)	5 (min.)
102	110	110	100	102	119.67	120	130.00	130	120	121.33	12400	14130	19550	18700	15360	14400
90	100	100	100	90	108.33	110	123.33	120	118	110.00	10150	12000	20400	16000	15500	13500
104	110	100	104	98	122.67	123	128.33	123	119	112.00	12800	12800	18480	18700	15000	12600
70	130	126	110	70	82.67	83	150.00	146	130	96.67	10584	11000	24320	22570	16900	14700
98	140	141	109	94	107.00	110	154.67	146	122	106.00	11250	13500	23000	20150	15288	12220
90	110	100	100	100	106.67	110	131.67	123	117	120.00	11200	13500	21875	17000	15000	16000
90	100	100	104	100	103.33	110	124.00	122	123	113.33	10400	12600	22360	19800	16000	12880
90	98	90	90	90	106.67	110	117.33	110	105	106.67	12600	13500	17160	15000	12060	12600
75	120	120	88	80	96.67	94	146.67	140	109	96.67	8680	8512	20400	15480	12000	9100
90	110	100	100	100	110.00	115	143.33	133	117	120.00	13200	14850	24150	22400	15000	16000
100	110	110	100	100	113.33	119	133.33	130	120	116.67	11200	15168	18000	16320	14400	13500
70	130	126	110	110	90.00	83	150.00	146	130	130.00	9750	8640	17480	15996	13520	13600
90	110	100	90	100	110.00	103	146.67	137	113	120.00	11400	11700	23760	22050	16960	14720
90	94	90	90	90	106.67	107	117.67	113	105	104.67	11480	11200	18150	16000	11424	10720
100	110	110	100	100	110.00	111	126.67	127	113	113.33	9360	11352	17440	15360	12600	11200
92	100	90	90	90	111.33	108	120.00	110	107	106.67	12000	12600	16000	15000	13440	13160
98	120	120	100	100	115.33	115	144.00	143	120	116.67	11250	14250	21504	20900	16000	15000
80	100	100	90	100	100.00	100	125.33	123	113	116.67	11200	11480	16896	16830	13760	12000
90	110	110	100	100	105.33	107	142.67	140	120	117.33	9520	10080	19136	17200	12000	10640
100	105	108	100	104	115.00	117	125.00	125	118	120.67	11890	14440	15510	14400	13950	13860
75	116	116	88	81	96.67	94	147.33	144	109	99.00	9940	12369	23100	21400	13680	11745
90	110	108	94	88	106.67	109		121	111	101.00	11760	13320	15000	14800	13920	11684
102	100	100	100	106	121.33	118	133.33	127	120	124.67	11200	12750	20000	16560	14400	14580
98	110	112	100	100	117.00	112	138.67	139	123	116.67	12400	14000	23520	21340	17000	13500
90	100	100	94	90	106.67	104	121.67	120	113	112.00	8960	9768	15675	13600	12000	10920
90	110	106	100	94	114.00	112	139.33	135	127	119.33	11340	11856	17028	16320	14400	13600
90	100	94	94	92	110.00	110	130.00	125	119	113.33	12000	14250	18620	17670	15120	14040
90	100	100	92	90	106.67	106	123.33	123	115	106.67	10640	11040	14450	13940	13120	10640
92	90	90	93	90	104.67	105	114.00	113	109	106.67	9100	9360	15390	14240	11480	11200
102	98	100	100	100	118.00	116	115.33	117	114	113.33	11250	11232	14100	12750	11360	11200